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Health Technology Assessment for Digital Health Technologies - An industry perspective on enabling innovation across Europe

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AI Artificial Intelligence

AR augmented reality

ATMP advanced therapy medicinal product

BfArM Bundesministerium für Arzneimittel und Medizinprodukte

CEUGrid-DMD Common European Classification Grid for Digital Medical Devices

DG Connect Directorate-General for Communications Networks, Content and Technology

DG Sante Directorate-General for Health & Food Safety

DHT Digital Health Technology

DiGA Digitale Gesundheitsanwendungen

DiPA Digital Pflegeanwendungen

DMD Digital Medical Devices

DoC EU Declaration of Conformity

DTx Digital therapeutics

DVG Digitale-Versorgung-Gesetz

e-PR Electronic Patient Records

EHDS European Health Data Space

EU European Union

EU4Health EU Health Programme

EUnetHTA European Network of Health Technology Assessment Bodies

EvalEUDMD European Taskforce for Evaluation of Digital Medical Devices

FDA United States Food and Drug Administration

FinCCHTA Finnish Coordinating Center for Health Technology Assessment

HaDEA European Health and Digital Executive Agency

HCP Healthcare Professional

HTA-R Health Technology Assessment Regulation

ICT Information Communication Technology

IHI Innovative Health Initiative

ISPOR International Society of Pharmacoeconomic and Outcomes Research

JCA joint clinical assessments

MCDA multiple-criteria decision analysis

MDR Medical Device Regulation

MDD Medical Device Directive

mHealth Mobile Health

NB Notified Body

NICE United Kingdom National Institute for Health and Care Excellence

PECAN La prise en charge anticipée numérique

PREM patient-reported experience measures

PROM patient-reported outcome measures

RCT Randomized clinical trials

RWE Real-world evidence

ROI return on investment

SaMD Software as a Medical Device

SD Standard Deviation

SME Small and medium-sized enterprises

VR virtual reality

WHO World Health Organisation

1 Introduction

1.1 Rise of Digital Health Technologies

In recent years, digital health technologies (DHTs) have emerged as a key area of innovation in healthcare, reflecting broader shifts in technological capability, health system demand and patient expectations. Ageing populations, reflected in the EU median age reaching 44.7 years (EuroStat, 2025), a projected health workforce shortage of 10 million by 2030 (WHO, 2025a) and increasing prevalence of chronic diseases accounting for 74% of global mortality (WHO, 2025b) place significant pressure on health systems. At the same time, advances in digital infrastructure such as mobile connectivity, cloud technology, data storages and sensor technologies have created fertile ground for digital health solutions to emerge and scale. The COVID-19 pandemic further accelerated this shift, as health systems aimed to maintain access to care during periods of restricted mobility and increased demand, teleconsultations across OECD countries more than doubled between 2019 and 2021 (OECD, 2023). From telemedical consultation and symptom checkers to remote monitoring and mental health support apps, digital technologies increasingly became integrated into everyday health practices.

This shift is reflected in the large number and diversity of currently available DHTs. To date, more than 1 million health-related mobile applications have been created, although only approximately 340,000 remain active, with around 90,000 new applications launched in a single year (IQVIA, 2024). An estimated 220 DHTs are used in day-to-day clinical practice globally, with around 140 having obtained market access through national regulatory or reimbursement pathways (IQVIA, 2024). These trends have continued in subsequent years, particularly in therapeutic areas like mental health, diabetes, cardiovascular disease and musculoskeletal conditions. The growing presence of DHTs in strategic health planning suggests that digital transformation is no longer viewed as an isolated innovation effort, but as a broader shift in how healthcare systems operate and deliver value.

Despite this growing role, the integration of these technologies into routine care remains uneven. Factors that impact uptake of DHTs include national health policies, properties of DHTs, patient characteristics, health professional characteristics, with robust regulatory and market access frameworks appearing as a primary factor (Van Kessel, Roman-Urrestarazu, *et al.*, 2023). A growing number of national and international policy initiatives are beginning to shape their development, evaluation, and adoption, yet the mechanisms that govern their market access are still evolving. These developments raise important questions about how DHTs are defined, how their value is assessed and what policy frameworks are needed to

ensure their safe, effective and equitable use (Zah et al., 2022). The following sections explore these issues by introducing the concept of digital health technologies, examining the regulatory and policy landscape that supports their uptake and identifying emerging challenges in evaluating their impact.

1.1.1 From innovation to validation

DHTs are developed by a diverse range of actors, including startups, small and medium-sized enterprises (SMEs), large multinational technology and pharmaceutical companies, academic research groups and even individual software engineers, many of whom have limited prior experience in putting health technologies on the market. While this diversity fosters rapid innovation and experimentation, it also introduces considerable variation in technological maturity, clinical relevance and robustness of evidence supporting these health technologies (Zah *et al.*, 2022; Alami *et al.*, 2024; OECD, 2025). The absence of formal entry barriers or standardised quality control mechanisms for many DHTs means that almost anyone can design and publish a health app, sometimes without undergoing clinical validation or regulatory appraisal. While some of these solutions may deliver meaningful benefits, others risk providing misleading information, insufficient data protection or inadequate performance for safe use in clinical settings (IQVIA, 2024).

The highly uneven levels of validation and endorsement of technologies within the digital health landscape is creating uncertainty for both users and decision-makers during implementation into routine care. Consequently, robust evidence is becoming an increasingly central factor in shaping institutional adoption and market success. DHTs supported by rigorous clinical validation are significantly more likely to be endorsed by healthcare professionals, professional societies, government agencies and patient organizations, facilitating their transition into routine care (Baumgart, 2011; Blease, 2023). This indicates that evidence generation may increasingly determine which digital solutions are successfully integrated into health systems and which remain marginal.

These developments suggest that innovation in digital health must be accompanied by appropriate and proportionate validation efforts. Tailored evaluation approaches are needed to ensure that innovation is balanced with safety, clinical value and trust. If implemented effectively, such approaches could enable digital transformation to become not only disruptive but also equitable and sustainable, supporting more accessible healthcare for European citizens while delivering personalised and value-driven care to patients.

1.1.2 Potential Value and Emerging Risks

DHTs may enhance care independently or work as add-ons to pharmaceuticals, clinician-delivered therapies and other medical devices. They have the ability to positively impact the outcomes of specific diseases or disorders, in addition to providing benefits such as optimizing the overall health status of patients, improving clinician effectiveness and efficiency, lowering overall healthcare system costs and strengthening public-health functions by improving support surveillance and system performance monitoring (European Centre for Disease Prevention and Control, 2022; OECD, 2023). Additional potential benefits include reduced travel and waiting times to receive care, reduced exposure to spread of infection, increased patient confidence in self-managing chronic conditions (European Commission, 2018d). Most of these benefits, however, can only be realised if users are supported appropriately, meaning they have knowledge on how to use the technology, the DHT is interoperable with currently used solutions, change management is supported if switching from current standard of care, and problem solving is supported if issues during usage are encountered (Drury *et al.*, 2018).

With the potential benefits come risks that are unique to these technologies. DHTs commonly collect a large amount of personal data and with this, threats to patient privacy from inadequate cybersecurity arise. Other risks include the use of incorrect patient information from poor interoperability or data quality management, ethical threats like incorrect interpretation of test results without clinician supervision and the false sense of security from being monitored (Kidholm *et al.*, 2012; Department of Health & Social Care (UK), 2021). Furthermore, DHTs that promote behavioural change often use this data to develop predictive behaviour algorithms (Sax *et al.*, 2018). Technology companies may also use transmissions of data with linkable user identifiers from DHTs for undesirable marketing and analytics purposes (Huckvale *et al.*, 2019). These unique risks need to be considered in addition to the risks of other health technologies, e.g. not effective treatments, potentially missed diagnoses, misclassification of disease severity as well as the inequity in access where there is poor connectivity or infrastructure. To realise the benefits and minimise risks, a robust evaluation process is essential to inform decision-makers on funding and planning all new health technologies, including DHT interventions.

1.2 Defining Digital Health Technologies

Given these benefits and risks, it becomes increasingly important to clarify what qualifies as a DHT, how they are categorised and what frameworks govern their development and evaluation. The European Commission (2025a) defines digital health as "a set of tools and services that use information and communication technologies (ICTs) to support and improve all stages of healthcare, from prevention and diagnosis to treatment, monitoring, and management of health conditions". DHTs therefore, may encompass a wide array of digital tools and applications that aim to enhance individual and population health outcomes, improve healthcare delivery or support system efficiency.

The term is often used as an umbrella category covering diverse technologies such as electronic patient records (ePRs), mobile health (mHealth), digital therapeutics (DTx), telemedicine, wearables, sensors, virtual reality (VR), augmented reality (AR) and artificial intelligence (AI) solutions (Awad *et al.*, 2021; Mbunge *et al.*, 2021; Digital Therapeutics Alliance *et al.*, 2023; Motahari Nezhad, 2023; OECD, 2025). Some definitions of DHTs also encompass robots that enable precision surgery, rehabilitation, medication dispensing and treatment (Awad *et al.*, 2021). These technologies can serve a wide range of functions, from improving patient well-being, processing patient data, performing independent care for therapeutic purposes as well as for health system improvement, public health preparedness or research and innovation (Digital Therapeutics Alliance *et al.*, 2023; OECD, 2025).

Despite their growing presence in health systems, there remains no universally accepted definition or classification system for DHTs. The terminology may differ across regulatory agencies, academic publications and industry stakeholders, often reflecting varying degrees of technical sophistication, clinical risk or intended use. While some DHTs may be regulated as medical devices, such as Software as a Medical Device (SaMD), others may function outside formal medical regulatory frameworks, targeting wellness or lifestyle changes. In fact, many of these solutions operate in a grey zone between clinically validated interventions and consumer wellness products. Whether or not a DHT is subject to medical device regulation depends primarily on its intended use and risk profile (European Parliament, 2025). This distinction is particularly important in the European context, where the classification of a DHT as a medical device determines whether it must comply with the EU Medical Device Regulation (MDR) and obtain a CE-mark before being marketed.

This heterogeneity makes it difficult to draw clear boundaries around what constitutes a DHT and what standards of evidence or oversight should apply. The lack of consistent classification may create challenges for validation, evaluation and integration of DHTs, particularly in the context of health technology assessment (HTA) and reimbursement. Without clear categories, it becomes difficult to compare tools, assess value or align evidence requirements (Mezei *et al.*, 2023; Zrubka *et al.*, 2024; Boers *et al.*, 2025). As a response to this ambiguity, several organisations, including the World Health Organization (WHO), the Digital Therapeutics Alliance, the International Society for Health Economics and Outcomes Research (ISPOR) and the European Taskforce for Harmonised Evaluation for Digital Medical Devices have begun to develop preliminary typologies and taxonomies (e.g. WHO CDISAH, PICOTS-ComTEC, CEUGrid-DMD). These efforts aim to clarify what types of DHTs exist, what they are designed to achieve and how they might be assessed in a consistent and transparent way. The following section outlines how the MDR and CE-marking requirements apply to digital health technologies, particularly those classified as medical devices, and how these regulatory processes influence their pathway to market.

1.2.1 MDR & CE-mark

In the European Union (EU), technologies classified as medical devices must comply with the requirements set out in the Medical Device Regulation (MDR) 2017/745 and bear the CE-mark before entering the market (European Parliament, 2025). The MDR, which replaced the Medical Device Directive (MDD) 93/42/EEC in 2021, represents a significant shift in regulatory approach. Among its aims are the strengthening of safety and performance standards, improved traceability and more robust post-market surveillance. Transition periods of the regulation vary in duration based on the risk classification of the device (European Parliament, 2025).

One of the key criticisms of the MDD was the lack of classification for Software as a Medical Device (SaMD), which has been rectified in the MDR (IMDRF SaMD Working Group, 2014; Kyhlstedt, 2022). Under the MDR, DHTs will be categorized as SaMD if their intended purpose involves diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease. The MDR outlines four risk classes (I, IIa, IIb, and III) for SaMD, with classification rules outlined in MDR Rule 11 in Annex VIII. Class III represents the highest risk category, typically applying to software that informs diagnostic or treatment decisions with potentially severe consequences, including death or irreversible deterioration of health. Class

IIb applies to tools that are used in managing serious conditions or that directly inform therapeutic decisions, such as calculating dosages or influencing treatment selection. Class IIa includes software that informs clinical decisions for non-critical conditions, where incorrect use may result in mild or reversible harm, while Class I refers to low-risk applications, such as self-monitoring tools (European Parliament, 2025). For low-risk (Class I) devices, the manufacturer may self-certify compliance, however, for higher-risk devices (Class IIa, IIb, and III), a conformity assessment conducted by a designated Notified Body (NB) is required. The assessment of the product's conformity, includes a comprehensive review of the technical documentation, covering aspects of product design, manufacturing processes, intended use and risk management (European Parliament, 2025).

The CE-mark signifies that the technology manufacturer or an authorized representative declares that product's conformity with applicable EU legislation. This allows the product to be marketed and circulated freely within the EU. In parallel, an EU Declaration of Conformity (DoC) must be prepared and signed, confirming that the device meets the relevant legal and regulatory requirements. The act of signing the DoC places full legal responsibility for compliance on the manufacturer or their representative (European Parliament, 2025).

1.3 Market entry pathways for DHTs

1.3.1 Market entry pathways and uptake mechanisms

Digital health technologies can enter healthcare systems through a variety of mechanisms, reflecting the decentralised and fast-paced nature of digital innovation. These pathways range from informal direct-to-consumer models to more formal, regulated pathways tied to public reimbursement. While each route has different implications for evidence, oversight and patient access, most do not fully align with a comprehensive or coordinated policy approach. To support safe, evidence-based and equitable integration of DHTs, Coder et al. (2024) propose a "full-stack" policy model consisting of four interlinked components: 1) regulatory authorization, 2) product value assessment, 3) pricing and reimbursement and 4) patient access infrastructure. Although this model offers a vision for systematic integration, most current market entry routes reflect only part of this structure.

One pathway is top-down policy-driven adoption, where digital technologies are implemented as part of national public health strategies or emergency responses. For example, during the COVID-19 pandemic, governments rapidly implemented DHTs such as contact-tracing

applications and vaccination tracking platforms. In such cases, regulatory authorization may be accelerated or adapted to facilitate rapid market access and value assessment is typically absent.

A common bottom-up pathway for DHTs to enter the market particularly in areas such as mental health, fitness and chronic disease management, is direct-to-patients models. These technologies are typically marketed directly to patients via mobile platforms and app stores, allowing individuals to adopt and pay out-of-pocket for DHTs they see as valuable. If the product is not classified as a medical device, regulatory authorization does not apply and product value assessment is typically absent. While this route facilitates accessibility and rapid uptake, it may bypass regulatory scrutiny and pose risks related to quality, privacy or clinical utility (OECD, 2025).

Another pathway is provider-based procurement (e.g. healthcare provider, pharmaceutical sponsors). This is typically driven by institutional priorities of hospitals and clinics around efficiency, clinical utility or operational need. While regulatory authorization (e.g. CE-marking) is generally a precondition for procurement, formal product value assessment is often limited to local evaluations or pilots (NHS, 2020). Pricing is negotiated directly with technology developers and is typically outside the scope of national reimbursement schemes. However, some systems are beginning to shift toward value-based procurement models that consider broader dimensions of value, including patient outcomes, integration with existing services, and long-term cost-effectiveness (EIT Health, 2022). Though still in early stages of adoption, value-based procurement may offer a more structured and evidence-oriented mechanism for the uptake of digital health technologies in clinical settings, particularly where traditional HTA is not required or feasible. Pharmaceutical and med-tech companies also play a role in enabling market access by integrating DHTs within existing therapeutic packages. In this case, technologies are often positioned as value-added services to already existing pharmaceutical or MedTech products to support adherence, enable remote monitoring or offer educational content (EFPIA, 2022). Regulatory authorization is usually ensured via the core product (e.g. drug or medical device), while standalone value assessment of the digital component may be limited.

Another market access pathway involves formal assessment and reimbursement pathways through third-party payers (e.g. health insurance). Among the available market entry pathways

these are the most likely to reflect the full-stack policy model proposed by Coder et al. (2024). This includes statutory or private health insurance, that can choose to cover or recommend digital health solutions as part of their benefit packages[1]. These schemes typically require regulatory authorization (CE-marking under the MDR) or equivalent evidence, and rely on structured processes for evaluating value, including formal health technology assessment (HTA) or similar value assessment procedures that provide additional evidence regarding cost-effectiveness, clinical benefit and real-world impact (EUnetHTA, 2022; European Commission, 2023a). Decisions are typically driven by evaluations of cost-effectiveness and customer demand and may incentivise uptake even in the absence of national reimbursement schemes. These are typically followed by price negotiations or tariff setting, and mechanisms for prescribing these technologies or systematic patient access. Nonetheless, reliance on traditional HTA and reimbursement processes may also introduce access delays or barriers in the rapidly evolving field of DHTs and limit timely access to technologies that improve health outcomes. This tension has prompted interest in tiered or proportionate evaluation frameworks, which aim to balance innovation support with evidence and safety expectations (OECD, 2025).

The above pathways showcase some of the mechanisms through which DHTs may enter the market, each with different implications for regulation, evidence and user access. While informal and decentralised models may support early uptake, formal reimbursement through public payers remains a critical enabler of large-scale and sustainable integration. Beyond its financial function, reimbursement often signals that a technology meets defined thresholds of safety, effectiveness, and value and in many systems serves as a gateway to clinical legitimacy and professional acceptance. This is particularly evident in predominantly public payer healthcare systems, where national and local purchaser determinations can enable or prevent access to safe, effective DHTs (Kelley *et al.*, 2020). This central role places HTA and reimbursement at the intersection of policy, practice and innovation, making it a key focus for emerging efforts to align digital health with existing healthcare structures.

The following section introduces the concept of HTA and explores its relevance, as a policy and decision-making tool and a potential framework for supporting the integration of digital innovation into health systems.

[1] In some countries the statutory scheme is administered by competing private insurers, so distinguishing "private" versus "statutory" insurers is not conceptually helpful in this context (e.g. the Netherlands, Switzerland).

1.4 Role of Health Technology Assessment

1.4.1 Defining Health Technology Assessment

Health Technology Assessment (HTA) is a "multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system" (O'Rourke *et al.*, 2020). It refers to the systematic evaluation of the effects and properties of health technologies, and its primary purpose is to support healthcare decision-makers in the adoption of new health technologies (Panteli and Busse, 2019; WHO, 2019). The World Health Organization (WHO, 2019) defines a health technology as "the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life." It can also be described as covering all interventions utilized to enhance health, prevent, diagnose, or treat acute or chronic diseases, and facilitate rehabilitation. These include pharmaceuticals, devices, methods and organizational systems used in healthcare.

The primary objective of HTA is to support healthcare decision-makers and those responsible for the procurement of health technologies, in making informed and evidence-based decisions. HTA is conducted using a multidisciplinary process that synthesizes systematically collected information in a transparent, unbiased, and robust manner (EUnetHTA, 2022). It involves the systematic analysis and evaluation of properties, effects and impacts of health technologies in clinical, economic, organizational, ethical and legal domains, both in the short and long term. In simple terms, the direct, intended consequences of technologies as well as their indirect, unintended consequences are evaluated. HTA has been used as a decision-making aid to address the problem of rising health care expenditures since the 1980s. As the number of health technologies is rising globally, there is a continued need to systematically assess value of technologies in order to achieve efficient and equitable resource allocation in health systems.

An essential aspect of HTA is evaluating the degree to which HTA reports can impact health policy and clinical practices (O'Rourke *et al.*, 2020). Despite having good and comprehensive HTA reports, their impact on decision-making may remain limited without a formal process for using HTA (Sihvo *et al.*, 2017). In contexts where HTA is not institutionalised into policy frameworks, reports may remain as technical documents with limited influence on actual decision-making. This creates inefficiencies, as resources are invested into generating evidence

that is not effectively translated into policy actions. Moreover, weak integration of HTA into policy undermines its potential to provide transparency and consistency in decision-making, which are among the key rationales for its development.

For health technology developers, HTA represents a critical gateway to market access and public reimbursement. Conducted according to established methodological standards and embedded into national health policy pathways, HTA informs decisions about whether a technology will be adopted, reimbursed or scaled within a national health system. In the EU context, where healthcare systems are largely tax-funded or social insurance-based, HTA outcomes often directly influence reimbursement decisions and integration into care pathways. As such, developers must understand and anticipate HTA requirements early during the development of their technology, particularly in markets where HTA outcomes determine or heavily influence pricing, reimbursement and procurement decisions.

For the context of this dissertation, I use "HTA" and "HTA framework" as a structured, domain-based and methodologically explicit specification, as well as the procedural rules utilised by a HTA authority or mandated body to appraise a health technology for policy or reimbursement decisions. A HTA framework sets out the core assessment domains, topics, sub-topics, the evidence standards and acceptable methods for each domain, and how results are synthesised to inform decisions. It may draw on generic domain models and be adapted to specific technology classes, decision problems and lifecycle stages, including re-assessment when new (real-world) evidence becomes available (Kidholm *et al.*, 2017; O'Rourke *et al.*, 2020; EUnetHTA, 2022).

1.4.2 HTA landscape in Europe

While the principles and methodologies of HTA are becoming increasingly formalised, its governance remains primarily a national responsibility across the European Union. Core principles of HTA are widely shared, but its implementation is shaped by the organisational, political and structural characteristics of each country's healthcare system. This results in notable differences in how assessments are conducted, what criteria are prioritised and how HTA outputs are used to inform policy and reimbursement decisions. These national variations, while reflecting local priorities and capacities, contribute to fragmented approaches across Europe (Zah *et al.*, 2022; Mezei *et al.*, 2023; Tarricone *et al.*, 2024).

Most European countries have established national HTA bodies or agencies, although their mandates, resources and procedural requirements may vary significantly. A 2018 mapping by the European Commission identified 56 HTA organisations across the 27 EU Member States and Norway, revealing a broad spectrum of institutional arrangements (European Commission, 2018b). In 15 Member States, a single national HTA body is responsible for producing assessments or coordinating HTA activities. In 12 others, multiple organisations are involved in various stages of the HTA process. Some operate under ministries of health, others are embedded within regulatory or insurance bodies, and many differ in terms of mandate, scope, and methodological rigour. As of 2023, nearly all Member States have at least one institution formally conducting HTA, though the maturity and formality of these processes remain uneven (European Commission, 2023b). A few Member States still lack formalised HTA systems or apply them only in limited policy areas.

This fragmentation creates a complex landscape, where health technologies may undergo multiple assessments with different standards, timelines and evidentiary expectations before gaining access across countries. While such diversity reflects differences in national health systems, it can also contribute to inefficiencies and delayed patient access, particularly for digital health technologies, which are often developed for scalable or cross-border use. As a response, several collaborative efforts have aimed to improve consistency and reduce duplication across national HTA systems, most notably through EUnetHTA and the forthcoming EU HTA Regulation. The following section introduces one of the most widely used reference frameworks designed to support this collaboration, the HTA Core Model.

1.4.3 HTA Core Model

A common reference framework for assessing health technologies in the European region is the HTA Core model. It was first introduced as part of the EUnetHTA Project in 2008 and has since undergone several updates to support methodological convergence in Europe. Its primary objective is to offer a standardized framework for producing and disseminating HTA evidence, facilitating collaboration between European countries by preventing the duplication of efforts (EUnetHTA, 2022).

The HTA Core Model covers nine domains: (1) the health problem and current use of technology; (2) description and technical characteristics of the new technology; (3) safety; (4) clinical effectiveness; (5) cost and economic effectiveness; (6) ethical analysis; (7)

organizational aspects; (8) patient and social aspects; and (9) legal aspects (Gyldmark *et al.*, 2018; EUnetHTA, 2022). In each domain, the HTA Core model describes elements which are questions to be answered in the HTA. Elements are organised within each domain into topic categories. The model shows interdependencies between topics and domains and the relevance of topics to different types of health technologies. If an assessment process covers all nine domains of the HTA Core Model, it is considered a full HTA. Alternatively, a rapid relative effectiveness assessment (REA) consists of only the first four domains. In the HTA Core Model, the last five domains are context-specific, while the first four are considered essential and transferable across different European countries (EUnetHTA, 2022).

While the HTA Core Model offers a comprehensive and widely accepted structure, its applicability to newer categories of technologies, such as digital health interventions, remains a subject of discussion. Notably, the model does not explicitly address features that may be critical for DHTs, including interoperability, cybersecurity, user engagement, or the dynamic nature of software updates and data integration. These limitations suggest that while the HTA Core Model provides a useful baseline, it may need to be adapted or expanded to ensure that assessments remain fit-for-purpose in the context of digital technologies. This issue will be explored further in the next section, which addresses methodological challenges in the evaluation of DHTs.

1.5 The case for Health Technology Assessment reform

1.5.1 Methodological challenges in HTA of DHTs

Traditional HTA processes have matured in the context of pharmaceuticals for decades. When HTA approaches were extended to medical devices, methodological and governance challenges already began to surface. Medical devices differed from pharmaceuticals in their regulatory treatment, pace of development and availability of clinical evidence, which made it difficult to apply HTA in a consistent and standardised way (Boers, 2020; Motahari Nezhad, 2023). In the case of DHTs, the methodological challenges surround HTA appear even more complex. Several interrelated characteristics of DHTs appear to challenge current HTA approaches. These include agile development cycles, user-dependent effectiveness, context-specific implementation outcomes, systemic impacts, significant variability even among similar tools and the absence of a standardised classification system. The following sections examine each of these issues, drawing on recent research and policy literature to identify emerging methodological needs.

1.5.1.1 Agile development cycles & evidence generation models

The development cycles of DHTs tend to be much shorter than those of pharmaceuticals and medical devices, with software updates and new features often released based on user feedback or agile design principles. Many DHTs are developed using design thinking approaches, which prioritize iterative prototyping, early end-user engagement, and rapid feedback loops to tailor solutions to real-world needs (Gualtieri *et al.*, 2022; Wang *et al.*, 2024). While this human-cantered approach enhances usability and adoption, this continuous evolution poses complexity for HTA, which traditionally relies on evaluations of a static pharmaceutical molecule or fixed medical device configuration. One of the most frequently raised methodological concerns is the mismatch of traditional data generation models, like randomised controlled trials (RCT) and the realities of digital innovation.

While RCTs remain the gold standard for evaluating clinical interventions, their applicability to DHTs is limited for several reasons. First, DHTs often evolve rapidly through iterative software updates, meaning that the version assessed in an RCT may no longer be current by the time results are published, reducing the validity and timeliness of findings. Second, DHTs are frequently co-developed and refined based on user feedback, which makes them inherently dynamic and less amenable to the fixed protocols and static interventions required in RCT designs. Third, the effectiveness of many DHTs depends not solely on the intervention itself, but also on how they are used, making outcomes highly dependent on factors such as user engagement, digital literacy and adherence. These user-dependent variables are typically controlled for or excluded in RCTs, yet they may be central to real-world effectiveness.

Moreover, many DHTs are deployed in complex, context-specific environments where organizational readiness, infrastructure and integration into existing workflows can significantly shape outcomes. Standard RCT settings may struggle to capture these contextual influences. Alternative evidence generation methods, such as real-world data (RWD) and simulation models, have been proposed to better capture the dynamic nature of DHTs (Alami et al., 2024; Brönneke et al., 2023; Hendricks et al., 2018). However, the integration of these methods into HTA frameworks remains inconsistent, necessitating a re-evaluation of assessment methods to accommodate characteristics of digital innovations.

This challenge is not unique to DHTs. Similar issues are observed in other emerging health technology domains such as cell and gene therapies, orphan drugs for rare diseases, and personalized medicine. These technologies often face methodological and ethical constraints that limit the feasibility of traditional RCTs, prompting calls for the development of alternative evidence standards. Initiatives such as the GetReal project and the EHDEN have actively explored how real-world evidence can be incorporated into HTA and regulatory decision-making across various types of innovative therapies (IHI, 2013; EHDEN, 2022; Motahari-Nezhad *et al.*, 2022). These developments highlight that the need for more adaptive and context-aware assessment frameworks extends beyond digital health and may offer opportunities for mutual learning across domains of health innovation.

1.5.1.2 User interactivity & User dependent outcomes

Many DHTs operate in environments characterised by high interactivity and decentralised use. Their effectiveness may be influenced not only by the product itself, but by how it is used, who uses it, and under what conditions. Factors such as user digital literacy, engagement levels, and adherence can significantly influence effectiveness (Hendricks *et al.*, 2018; Alami *et al.*, 2024). For example, a mobile health application designed for chronic disease management may demonstrate varying efficacy depending on individual user engagement and understanding. Traditional HTA methodologies often overlook these user-dependent variables, leading to assessments that may not fully capture the real-world performance of DHTs.

In this context, the inclusion of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) may offer a valuable supplement to conventional evaluation approaches. PROMs capture patients' self-reported perceptions of their health status, functionality, or wellbeing following the use of a technology, while PREMs assess the quality of interactions, accessibility, and perceived usefulness of a service or tool. Originally used in research and clinical benchmarking, these tools are increasingly seen as critical components of value-based and person-centred healthcare systems (Bull and Callander, 2022). Incorporating user experience metrics and behavioural data into HTA processes is essential to provide a comprehensive evaluation of DHT effectiveness (Haverinen *et al.*, 2019).

1.5.1.3 Organizational impact

When DHTs are implemented, they can prompt significant shifts in healthcare workflows and communication patterns. For example, the integration of electronic health records (EHR) or

AI-enabled clinical decision support tools may necessitate reconfiguration of team dynamics, adaptation of scheduling systems and new training procedures for health professionals (Greenhalgh *et al.*, 2017; Kelley *et al.*, 2020). While such systemic changes may yield long-term benefits, including improved efficiency and patient outcomes, their implementation can be highly resource-intensive including operational challenges, especially if organizational readiness is limited or poorly aligned with the technological change (Mair *et al.*, 2012). These aspects are rarely captured in conventional HTA processes, which tend to focus on clinical and economic outcomes at the individual level. Yet, emerging evidence suggests that the organizational impact of DHTs may significantly influence their effectiveness, scalability, and sustainability (Cresswell & Sheikh, 2013; Ludwick & Doucette, 2009). As a result, scholars increasingly call for HTA frameworks to incorporate system-level and context-sensitive dimensions of evaluation, including implementation costs, workflow integration challenges, and long-term institutional adaptation strategies (Kelley *et al.*, 2020; Burrell *et al.*, 2022; Haverinen *et al.*, 2022).

1.5.1.4 Context dependent effectiveness

Effectiveness of digital health solutions is heavily shaped by their local implementation context. These include the digital maturity of national infrastructures, organizational readiness, existing clinical workflows and local policy frameworks. Countries or institutions with robust eHealth infrastructures and coordinated digital strategies may provide more fertile ground for the adoption and sustained use of DHTs. In contrast, fragmented systems, limited interoperability or inadequate training environments may hinder the implementation and impact of the same technologies (Essén *et al.*, 2022). For example, a telemedicine platform may perform well in an urban hospital with strong digital infrastructure but may encounter limitations in rural areas where internet connectivity is limited. These contextual variables suggest that the outcomes of a DHT cannot easily be generalized across settings. Instead, they highlight the importance of HTA processes being sensitive to local implementation environments and that consider scalability and transferability as part of the assessment. Without this sensitivity, assessments may overlook critical enablers or barriers to real-world effectiveness (Haverinen *et al.*, 2019).

1.5.1.5 Variability Even Among Similar DHTs

A particularly challenging feature of DHTs from an assessment perspective is their pronounced variability, even within narrowly defined functional categories. Minor differences in user

interface, gamification elements, reminder systems or data visualization techniques can substantially influence user engagement and by that the effectiveness of the tool (Höchsmann *et al.*, 2019; Ossenbrink *et al.*, 2023). For instance, apps with similar glucose monitoring capabilities may differ in how they prompt users, how frequently they encourage data input or how they visualize trends, resulting in very different patterns of adherence and clinical outcomes. Such discrepancies complicate HTA efforts because the findings from one DHT cannot be reliably generalized to another, even when their functional profiles appear closely aligned (Zrubka *et al.*, 2024).

This variability introduces uncertainty into the evaluation and reimbursement process, as decision-makers cannot assume that evidence from one product is transferable to similar tools. Lantzsch et al. (2022) emphasize the importance of establishing more granular categorization systems that recognize meaningful differences between digital tools. Without such differentiation, HTA frameworks risk either overgeneralizing, leading to inappropriate adoption decisions, or overburdening evaluators with the need for redundant assessments of functionally similar products.

1.5.1.6 Lack of standardised taxonomy & classification

Importantly, the lack of a standardised taxonomy or classification system for DHTs complicates the assessment process further. Unlike pharmaceuticals, which benefit from internationally standardised classification systems (e.g., ATC codes), or medical devices, which are subject to established regulatory categories and conformity processes under the Medical Device Regulation (EU 2017/745), DHTs often fall between regulatory definitions or span multiple functional roles. This ambiguity can result in divergent interpretations of what constitutes a DHT, how it should be categorized, and what evidence is necessary for its evaluation and uptake (Lantzsch *et al.*, 2022; Zrubka *et al.*, 2024).

Emerging classification proposals, such as the Common European Classification Grid for Digital Medical Devices (CEUGrid-DMD) developed by the EvalEUDMD Taskforce, aim to address this gap by proposing a structured taxonomy that classifies DHTs according to intended use, user group, and clinical context (Boers *et al.*, 2025). This classification includes categories such as Inform, Diagnose, Manage, Monitor, and Treat, each of which is associated with different evidence needs and assessment dimensions. Such structured approaches may facilitate clearer alignment between the nature of the technology and the domains to be evaluated in

HTA, including aspects like clinical effectiveness, user experience, interoperability, and cybersecurity.

Furthermore, without a clear taxonomy, HTA bodies may struggle to define relevant comparators, appropriate endpoints or minimum standards for evidence. The PICOTS-ComTeC framework, proposed by ISPOR Special interest Group for Digital Health illustrates how tailored structuring of evaluation elements, such as context, technology characteristics and comparator selection, can support more appropriate and nuanced DHT assessments (Zrubka *et al.*, 2024). A lack of such frameworks may also limit the potential for cross-national collaboration in HTA, which is a stated objective of the HTA Regulation (EU 2021/2282). In this sense, harmonising taxonomies is not merely a technical exercise, but a prerequisite for scalable and efficient evaluation and adoption of DHTs across health systems.

In summary, the assessment of DHTs presents distinct methodological challenges that may not be adequately addressed by traditional HTA approaches developed for pharmaceuticals and medical devices. Rapid development cycles, user-dependent outcomes, context-specific effectiveness and systemic impacts complicate standard evidence generation and evaluation. Moreover, the variability between similar tools and the absence of a harmonised classification system may limit comparability, reproducibility and informed decision-making. These limitations suggest that current HTA frameworks, while grounded in important principles of rigour and transparency, may require methodological innovation to remain relevant and responsive to the evolving nature of digital health.

1.5.2 HTA as innovation policy instrument

In addition to methodological challenges within HTA, there is a deeper mismatch between current HTA processes and the dynamics of digital health innovation. Beyond methodological questions, HTA interacts with wider policy dynamics and can significantly shape the conditions for digital innovation. Understanding HTA as part of the broader European policy mix highlights both its potential as an enabling instrument and the risks of misalignment (Flanagan, Uyarra, & Laranja, 2011).

HTA does not operate in isolation but functions as part of a wider policy mix that includes regulatory instruments such as the MDR, data infrastructures, pricing and reimbursement frameworks and patient access infrastructures. Within this policy mix, HTA has a dual role:

ensuring evidence-based decision-making while also influencing whether digital health innovations can scale and be adopted. Yet, many of today's HTA practices remain rooted in pharmaceutical models that are poorly suited to the business logic of digital health. Pharmaceuticals rely on patents and long investment cycles that can tolerate lengthy assessments, whereas DHT developers often depend on subscription models, service contracts, or integration into care pathways, where return on investment is far more sensitive to time-to-market and early demonstration of value (Kidholm *et al.*, 2012; Haverinen *et al.*, 2019). Lengthy and resource-intensive HTA processes, when applied without adaptation, may therefore undermine not only the commercial viability of DHTs but also the societal return on public investments in digital health infrastructure and innovation programmes.

From a policy mix perspective, HTA is one instrument among many that influences the incentives and behaviour of technology developers. Its impact depends on how well it interacts with reimbursement mechanisms, industrial policies and digital health strategies, and whether it contributes to consistency, credibility and complementarity across these instruments. When embedded into a balanced policy mix, HTA can reduce uncertainty, legitimise investment, and support the formation of new markets for DHTs. In this way, HTA reform has the potential to move beyond cost-control towards actively enabling digital health innovation in Europe.

These dynamics suggest that HTA needs to be understood not only as a methodological toolkit, but also as a policy instrument embedded within Europe's broader innovation and health strategies. While substantial EU-level investments aim to accelerate the digital transformation of health systems, fragmented and resource-intensive HTA requirements may limit how quickly these investments can translate into patient access to innovative and technologies and therefore timely health benefits for the population. This framing underlines the importance of situating HTA reform in the wider policy mix, to ensure that assessment processes remain evidence-based while also being responsive to the speed, diversity, and characteristics of digital health innovation.

1.6 Emerging policy and market access pathways for DHTs

1.6.1 National pathways for DHT evaluation and access

There is an increasing interest in adopting digital health market access pathways incorporating HTA methodologies that reflect the specificities of digital solutions worldwide. These

initiatives suggest a growing recognition that traditional assessment models are not fully suited to the needs and characteristics of DHTs. As a result, national frameworks are emerging that aim to balance evidence requirements with innovation potential, while also safeguarding patient safety and sustainability of health systems.

1.6.1.1 DiGA Fast-track

Among the pioneering countries is Germany that introduced the DiGA Fast-Track (BfArM, 2019) in 2019 as part of the Digital Healthcare Act ("Digitale-Versorgung-Gesetz", DVG) (Bundesgesungheitsministerium, 2019). This pathway allows CE-marked low-risk DHTs or "Gesundheitsanwendungen*"* (DiGA) to be listed in the "DiGA Directory*"* and reimbursed by statutory health insurance following an application to the Federal Institute for Drugs and Medical Devices (BfArM). To be listed in the directory, developers need to demonstrate positive healthcare effects of the DiGA through medical or process- and structure-related outcomes. If developers cannot demonstrate sufficient evidence of positive healthcare effects at the time of the application, provisional listing is possible for up to 12 months (extendable to 24), during which time they must collect the necessary data based on prior consultations and detailed guidelines provided by BfArM. Approved DiGAs listed in the DiGA directory can be prescribed by physicians and psychotherapists to patients with corresponding indications. A parallel process, the DiPA Fast-Track (BfArM, 2023), developed for digital nursing applications, was implemented in 2023. DHTs entering the DiPA Fast-track don't need to be classified as medical devices, further expanding Germany's commitment to integrating DHTs into their national health system.

1.6.1.2 PECAN pathway

France's PECAN (Prise en Charge Anticipée Numérique) pathway (HAS, 2024b) was introduced in 2023 and shares similarities with DiGA. PECAN offers early and conditional funding for promising DHTs or Dispositifs Médicaux Numériques (DMN) through a provisional inclusion process led by the Haute Autorité de Santé (HAS). Unlike DiGA, that targets solutions with low-risk profiles, PECAN includes devices of higher risk classes (MDR IIb and III) as well, and can allow access even before CE-marking in specific cases, if sufficient early clinical or real-world evidence is available. The assessment prioritises clinical benefit, usability and alignment with care priorities, while also requiring commitments from developers to generate further data. The program is embedded in France's broader digital health strategy (French Ministry of Health, 2021), which seeks to mainstream digital innovation across the

healthcare system, with additional pathways specifically for telemonitoring DMDs, that can be registered in the list of remote medical monitoring activities ("Liste des Activités de Télésurveillance Médicale", LATM) and therapeutic software that can gain access to reimbursement through the standard medical device pathway if registering in the list of products and services qualifying for reimbursement ("Liste des Produits et Prestations Remboursable", LPP).

1.6.1.3 mHealth framework

Belgium's mHealth pyramid (RIZIV, 2021), launched in 2021 and it was originally structured as a three-tiered pyramid system, where DHTs could progress from CE-marking verification as a medical device (Level 1), proof of interoperability with the national eHealth platform, myHealth (Level 2) to demonstration of added value for patients, healthcare providers or the system (Level 3). Under the assessment process, developers were required to submit their application to the National Institute for Health and Disability Insurance (NIHDI), that activated an ad-hoc working group to assess the DHT. The mHealth framework was revised in 2023 to streamline the steps of assessment and link it more closely with reimbursement decision-making. The updated pathway puts a stronger emphasis on cost-effectiveness and health outcomes for Level 3 criteria and includes the establishment of a permanent multidisciplinary working group for assessment, as well as the formal inclusion of temporary reimbursement in the pathway.

1.6.1.4 Other national developments

Other countries are also developing relevant frameworks. Finland's Digi-HTA framework (Haverinen *et al.*, 2019), coordinated by FinCCHTA, uses a traffic light system (green, yellow, red) to rate availability and robustness of evidence for DHTs in multiple dimensions, including clinical effectiveness, safety, usability, cost and data protection. The aim is to support procurement and investment decisions by public hospitals and municipal providers, offering a rapid and transparent evaluation format tailored to the needs of smaller health systems. Although the assessment is non-binding and not connected to statutory reimbursement, a green rating often facilitates local adoption. The Evidence Standards Framework for Digital Health Technologies, developed by the National Institute for Health and Care Excellence (NICE) in collaboration with NHS England, sets out tiered requirements for evidence based on the technology's level of risk and function (NICE, 2024). It includes specific expectations around clinical effectiveness, economic impact, usability and data security. While not formally linked

to reimbursement, the framework is increasingly used to guide procurement, inform commissioners, and support early-stage investment decisions. In Spain's decentralised system, regional health authorities play a key role. A prominent example is Catalonia's AQuAS (Agency for Health Quality and Assessment of Catalonia)**,** which has developed a structured evaluation methodology for DHTs through its Digital Health Innovation Assessment Framework (Segur-Ferrer et al., 2024). This model is based on the HTA Core Model and includes assessment dimensions such as technological readiness, clinical value, economic impact, and ethical considerations. Although not yet part of a national reimbursement scheme, this regional model serves as a prototype for wider national adoption in Spain and abroad.

Together, these national initiatives highlight a broader policy shift toward accommodating digital innovation within existing reimbursement structures. While these frameworks are not uniform in their structure or legal basis, they share a common aim of linking evidence generation to funding decisions of DHTs. Despite these developments, the speed and depth of implementation remain uneven across Europe, shaped by national priorities, system readiness and available resources (Petracca *et al.*, 2020; Tarricone *et al.*, 2024).

While the above pioneering countries can serve as an example, low- and middle-income countries may be in need of methodological support on how to value, categorise and reimburse DHTs and must navigate DHT transformation carefully, as the available resources are even more limited compared to more affluent countries (Mezei *et al.*, 2023). These national initiatives also illustrate the ongoing evolution of HTA as a flexible policy tool in the context of digital health, that may require continued methodological adaptation to remain relevant and effective. The next section explores how collaborative efforts at the European and international level are beginning to build on this momentum, aiming to develop more harmonised and scalable approaches to DHT evaluation.

1.6.2 European and international collaboration efforts

Alongside national initiatives, a growing number of European and international efforts aim to support integration of DHTs across borders. These developments reflect a broader shift towards recognising DHTs not only as local innovations but as policy-relevant tools that could benefit from structured, shared learning and cross-country alignment. While the diversity of national health systems necessitates context-specific adaptations, joint initiatives may help reduce

duplication of efforts, support regulatory convergence and promote more consistent standards for evidence generation (MedTech Europe, 2021; EIT Health, 2022).

The European Commission and Member States have taken various steps to establish a coherent framework for digital health at the EU level. This includes coordinated strategies under the 2017 Council Conclusions on Health in the Digital Society (Council of the European Union, 2017) and the 2018 Communication on enabling the digital transformation of health and care (European Commission, 2018a). These policy efforts have emphasised the need to address challenges around interoperability, cybersecurity, medical device safety and data governance. Regulatory developments, such as the General Data Protection Regulation (GDPR), the European Health Data Space (EHDS) and the Artificial Intelligence Act (AI Act) are also contributing to an evolving policy landscape in which DHT evaluation must be situated. Recent developments also indicate a drive towards pan-European harmonisation of HTA processes and dedicated innovation access pathways, including methodologies to evaluate DHTs.

1.6.2.1 HTA-Regulation

HTA in Europe has undergone a significant evolution over the past decades, transitioning from voluntary cooperation towards more structured and legally binding forms of collaboration. This shift has culminated in the adoption of the Health Technology Assessment Regulation (HTA-R), formally known as Regulation (EU) 2021/2282, which entered into force in January 2022. The Regulation represents a landmark step in fostering greater coherence in HTA across EU Member States, aiming to reduce duplication of efforts, support timely access to innovative technologies, and enhance the overall sustainability of healthcare systems (European Commission, 2018b).

Beginning in January 2025, the HTA-R sets out a phased implementation roadmap, with binding provisions on joint clinical assessments (JCA). Initially, JCAs will apply to oncology medicines and advanced therapy medicinal products (ATMPs), followed by orphan medicines in 2028, and subsequently expanding to the full scope of health technologies by 2030. For medical devices, the Regulation currently includes a selection process targeting high-risk devices, particularly Class III and certain Class IIb products such as those incorporating software for drug administration (European Commission, 2023b). Under the HTA-R, only clinical evidence generated and assessed within JCAs is intended to be transferable across

Member States. Economic, organisational, ethical and other contextual domains of HTA remain under the purview of national authorities, reflecting the principle of subsidiarity.

Although the HTA-R represents a major step forward in harmonising HTA processes, DHTs remain uncovered by the binding mechanisms of the HTA-R. By design, the Regulation does not include low-risk class medical devices (Class I and many Class IIa), which represent a large portion of digital health solutions, including wellness apps, lifestyle tracking tools and some diagnostic aids. Furthermore, DHTs that are not classified as medical devices are entirely excluded from the Regulation. Further discussions are planned in a few years regarding voluntary cooperation by HTA agencies to assess all DHTs under the HTA-R (European Commission, 2023a).

1.6.2.2 European Taskforce for Harmonised Evaluation of Digital Medical Devices

Under the French Presidency of the Council of the European Union, a European Taskforce for Harmonised Evaluation of Digital Medical Devices (EvaluDMD Taskforce) was launched in April 2022. The EvaluDMD Taskforce builds on preparatory discussions initiated in late 2021 and brings together contributions from national authorities in France, Germany and the EUnetHTA network. Chaired by the Digital Health delegation of the French Ministry of Health and coordinated by EIT Health, it involves participants from Austria, Belgium, Spain, Finland, Germany, Italy, Luxembourg and other EU Member States with representatives from ministries of health, HTA agencies, policy advisors and academia.

The main goal of the EvaluDMD Taskforce is to foster voluntary alignment among European countries on key policy elements that may facilitate the future integration and evaluation of DMDs. This includes the development of a shared taxonomy and nomenclature, the proposal of harmonised classification principles, and the formulation of evidence expectations aligned with the intended use and application scope of different categories of DMDs (Boers et al., 2025). In the context of the HTA-R, the taskforce seeks to support the convergence between evaluations of DMDs in the EU, thereby enabling faster access for patients to these innovative solutions in the context of value-based healthcare. In this sense, the Taskforce functions as a policy initiative aiming to prepare the ground for future cross-border collaboration in DMD assessment, rather than as a distinct methodological body.

In line with its broader policy objectives, the taskforce maintains dialogue with stakeholders through a non-binding external advisory group, which includes representatives from digital health companies, consultancy firms, and contract research organisations from both EU and non-EU countries. Although its outputs are not formalised within legal or regulatory frameworks, the taskforce signals growing interest among policymakers to build shared foundations for the evaluation of DMDs across Europe, potentially enhancing alignment, efficiency and patient access in the years to come.

1.6.2.3 EDiHTA and Assess-DHT

Alongside regulatory developments and policy coordination efforts, several EU-funded projects have emerged to support the assessment and adoption of DHTs across Europe. These projects aim to develop methodological and procedural solutions that address the specific challenges posed by DHTs, while also contributing to the broader goal of fostering innovation and evidence-based health systems across Europe.

One such initiative is the European Digital Health Technology Assessment (EDiHTA) project, which this dissertation builds on both conceptually and through its involvement in the project's research activities. Launched in January 2024, and coordinated by Università Cattolica del Sacro Cuore, EDiHTA's mission is to develop a harmonized, flexible, and transparent HTA framework specifically tailored to the unique characteristics of digital health by mapping and addressing the regulatory and HTA barriers that limit the timely and equitable adoption of DHTs across Europe. Designed to target different type of DHTs, including telemedicine solutions, mobile health applications and AI-based tools, across different stages of maturity and healthcare contexts, the framework will enable the evaluation of a broad range of DHTs. A key strength of the EDiHTA initiative lies in its multi-stakeholder composition: the consortium brings together 16 partners from 10 countries, including HTA agencies, hospitals, patient organizations and academic institutions (EDiHTA, 2025).

The project adopts a stakeholder-centred approach from the early stages of framework development, with WP3 playing a central role in the design and validation of the methodology. WP3 is dedicated to co-creating the EDiHTA framework through systematic stakeholder involvement and governance mapping. This includes the identification and engagement of key actors, such as HTA agencies, healthcare providers, health technology developers, policymakers and patients, whose perspectives and needs are expected to shape the usability

and legitimacy of the final framework. The framework will be tested in real-world settings in prominent European hospitals and through an open piloting program involving DHT developers. This ensures that the framework is not only theoretically sound but also practically applicable across diverse healthcare contexts.

Running in parallel is the ASSESS-DHT project, coordinated by the British National Institute for Health and Care Excellence (NICE). ASSESS-DHT focuses on consolidating and streamlining existing methods and tools used for the assessment of DHTs. Its objective is to develop a fit-for-purpose, generic HTA framework that is harmonised at the European level but also sufficiently flexible to accommodate different healthcare settings. The project explicitly aims to align its outputs with the European Health Data Space (EHDS) Regulation and to respond to the methodological challenges associated with evaluating digital technologies, such as demonstrating added value, managing uncertainty and capturing the broader impact of DHTs on system transformation and patient outcomes (ASSESS DHT, 2024).

Both EDiHTA and ASSESS-DHT are funded under the same Horizon Europe call and share overlapping objectives in advancing the assessment and integration of DHTs within European healthcare systems. Recognizing the complementary nature of their work, the European Commission has encouraged collaboration between the two projects. This collaborative effort aims to ensure coherence and synergy in developing HTA frameworks, avoid duplication of efforts, and maximize the impact of their findings. By working together, EDiHTA and ASSESS-DHT aspire to contribute significantly to the establishment of robust, harmonized methodologies that will facilitate the seamless adoption of digital health innovations across Europe.

1.6.2.1 Other related policy development and EU initiatives

In parallel with regulatory reforms and collaborative HTA efforts, a number of broader European Union policy initiatives are shaping the conditions under which digital health technologies are developed, evaluated and adopted. These initiatives are not designed specifically for HTA, yet they establish critical infrastructures and regulatory environments that may influence how DHTs are assessed and integrated into healthcare systems.

The EU adopted its Digital Single Market strategy as one of the European Commission's 10 political priorities to create an environment where digital services and networks can prosper as early as 2015 (European Union, 2015). In 2017, EU Member States and the Commission set out to collaborate in view of enabling the Digital Single Market in health (European Commission, 2017). The EU's long-term funding programme, Horizon Europe, dedicated € 4.1 billion for the years 2021–2027 to support "Health", which now serves to generate new knowledge and develop innovative solutions in this area. Another € 95.5 billion has been allocated to "Digital, Industry and Space", which alongside "Health" is being implemented through the newly established European Health and Digital Executive Agency (HaDEA). The EU Health Programme (EU4Health), the largest of the health programmes ever launched, specifically in response to the pandemic, meanwhile € 5.3 billion was invested towards building a European Health Union and explicitly provides for reinforcing health data, digital tools and services and digital transformation of healthcare as a means of strengthening Europe's health systems.

A most recent example is the Regulation on the European Health Data Space (EHDS) (European Commission, 2025b), one of the central building blocks of the European Health Union and a milestone in EU's digital transformation. It aims to establish a framework that will empower individuals to take control of their own health data, while supporting the use of such data for better healthcare delivery, research and innovation and policymaking. If well implemented, it can give both healthcare systems and DHT developers an opportunity to evaluate the impact of introducing DHTs in real-world settings. It can also enable better access to data needed by DHT developers to train AI algorithms.

The EU Artificial Intelligence Act, currently being finalised, is also expected to have far-reaching implications for the digital health landscape. As a horizontal regulation with risk-based classification of AI systems, it may introduce new compliance requirements for DHT developers using AI while also clarifying expectations around safety, transparency, and performance. The Act's emphasis on high-risk AI, including in health applications, aligns with broader EU efforts to ensure that digital innovation does not come at the expense of user rights or health equity.

Several complementary initiatives aim to create supportive ecosystems for innovation and testing of digital solutions. EU initiatives such as the development of Testing and

Experimenting facilities (TEF Health) and the Innovative Health Initiative (IHI), as well as national initiatives proposing to build out living labs (e.g. in France and Luxembourg) aim to provide a supportive infrastructure to apply DHTs in care pathways (ISPOR, 2022; TEF Health, 2024; IHI, 2025).

Finally, other ongoing developments, including the rollout of the European Digital Identity framework, the implementation of the EU's Cybersecurity Strategy, and alignment with international strategies such as the WHO Global Strategy on Digital Health (2020-2025) may indirectly support DHT adoption by improving digital infrastructure, ensuring interoperability and enhancing trust in digital solutions.

These policy developments collectively shape a more supportive environment for the adoption and responsible integration of digital health technologies. As DHTs increasingly challenge traditional development processes and implementation pathways, there is a growing need to reconsider the role of HTA not only as a gatekeeping mechanism, but as a dynamic, forward-looking policy tool. The following chapter provides a conceptual lens for this transformation by drawing on insights from innovation management, offering both a theoretical framework and the foundational perspective through which my doctoral dissertation approaches the adaptation of HTA methods to digital health technologies.

1.7 Innovation in HTA

1.7.1 Innovation of HTA methods

Innovation is commonly defined as the successful implementation of a novel idea that creates value for its stakeholder, relating to a product, process or a structure (Varkey *et al.*, 2008). In the context of this dissertation, the definition of innovation implies that innovation encompasses not only introduction of new health technologies or digital tools, but also the continuous adaptation of the institutional arrangements through which these interventions are created, assessed, implemented and adopted. As noted by (Smets *et al.*, 2012), institutional innovation often emerges when existing systems repeatedly fail to accommodate new types of challenges, prompting a redefinition of actor roles, decision structures and evaluative standards. As the digital health ecosystem expands and diversifies, traditional HTA methods struggle to accommodate the complexity, context-dependence and rapid evolution of DHTs.
This phenomenon is increasingly visible as innovation-sensitive assessment models has led to the emergence of parallel efforts outside traditional HTA frameworks (see Chapter 1.6).

The need for such adaptation is increasingly recognised in policy and literature as well. Recent years have seen the emergence of structured approaches to support the innovation of HTA methodologies to keep up with innovative technologies. In 2012 a guideline was developed for evaluating and reporting discrete event simulation, a novel computer-based modelling applied in the HTA context (Karnon *et al.*, 2012). Another example is a recent report developed by the International Society of Pharmacoeconomic and Outcomes Research (ISPOR) to guide the developing and implementing multiple-criteria decision analysis (MCDA) to support healthcare decisions. Several other EU-funded projects have been working on methodological innovation of HTA processes and evaluation aspects to meet latest needs and provide the most fit-for purpose solutions for methodological, procedural and institutional challenges around evaluation and reimbursement of health technologies (Advance-HTA, 2015; Impact-HTA, 2018; HTx Project, 2020; Sustain HTA, 2025).

The next section introduces a conceptual framework that captures how methodological innovation in HTA can be systematically understood and supported.

1.7.2 IHTAM framework

In response to the need of innovating HTA methods, the Innovation of Health Technology Assessment Methods (IHTAM) framework was developed within the Horizon 2020 HTx project (HTx Project, 2020). The IHTAM framework offers a structured approach to understanding how HTA methods can evolve through stakeholder-driven processes (Jiu *et al.*, 2022).

The IHTAM framework breaks the innovation process into three distinct but interlinked phases: Identification, Development and Implementation (Figure 1). The Identification phase is concerned with recognizing the need for methodological change. This involves reflecting on the limitations of current HTA methods, learning from both past and present experiences, anticipating future challenges, and engaging with stakeholders to articulate new methodological needs (Jiu et al., 2022). The second phase, Development, focuses on translating identified needs into new or adapted methods. This includes the generation, testing, and refinement of novel methodological approaches, ensuring their technical robustness and relevance. Finally, the Implementation phase encompasses the real-world adoption, dissemination, and institutionalization of new HTA methods. This includes piloting and

iterative feedback, as well as alignment with broader policy and governance structures to enable systematic use (Jiu et al., 2022).

A key strength of the IHTAM framework lies in its emphasis on the dynamic and collaborative nature of methodological innovation. Rather than treating HTA as a static body of knowledge, it positions method development as a continuous and participatory process shaped by the actors who engage with it. In this, the IHTAM framework echoes broader models of institutional innovation, in which change is not only top-down, but emerges through processes of experimentation, negotiation, and shared problem-solving among diverse actors (Dooley and Van de Ven, 1999).

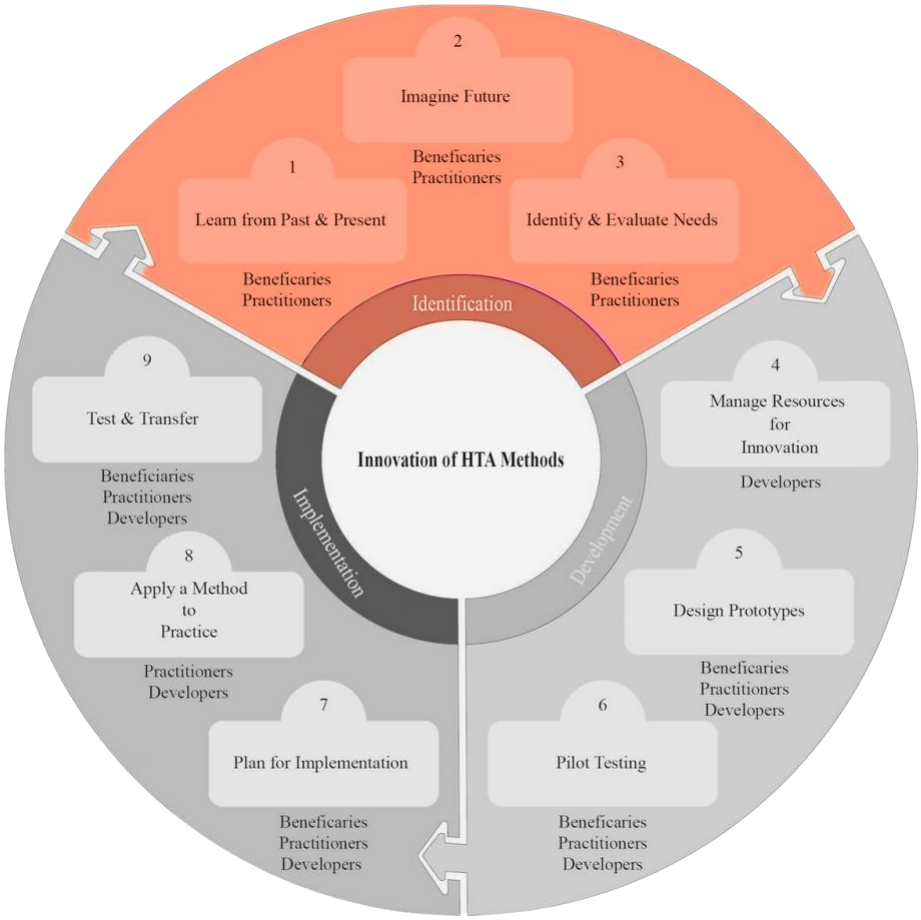


Figure 1: Key concepts of the IHTAM framework regarding innovation process of HTA methods. The three phases (i.e. identification, development and implementation) and roles of HTA stakeholders in innovation are described in each subphase. Marked in red is the scope of this dissertation: the identification phase. (Source: based on Jiu et a., 2022)

1.7.3 Stakeholder participation in innovation of HTA methods

Successful innovation in HTA methods requires active and inclusive stakeholder engagement. Vos and Achterkamp (2006) define stakeholders of an innovation process as “those parties that have an interest in the outcomes, of whatever kind, of that project” (Vos and Achterkamp,

2006). In the context of HTA, this includes not only HTA agencies, regulators and policymakers, but also healthcare providers, patients, payers and health technology developers, in other terms the industry.

The classic way of describing HTA stakeholders does not specify the roles they may take within innovation processes. A key strength of the IHTAM framework lies in its emphasis on the roles stakeholders play in each phase of innovation, rather than merely categorizing stakeholders by group (e.g., HTA agency, industry, patient). Stakeholders are instead seen as potentially shifting between roles - as beneficiaries, developers or practitioners, depending on the phase and context. This flexible, role-based approach provides a more realistic and inclusive lens for facilitating HTA innovation, as it acknowledges the dynamic nature of stakeholder engagement throughout the innovation lifecycle (Jiu *et al.*, 2022). It also aligns with contemporary thinking on co-production and deliberative processes in HTA, which emphasise the value of shared understanding, transparency, and mutual learning (Oortwijn *et al.*, 2022).

This broader emphasis on multi-stakeholder engagement is also supported by innovation research beyond the HTA field, which highlights that successful innovation processes, especially those occurring in institutional or policy domains require inclusive structures that facilitate interaction between different knowledge domains and actor types (Dooley and Van de Ven, 1999). In the context of HTA, this means engaging with policymakers, payers, clinicians, academics, patients and industry not just as recipients of new methods, but as co-creators of them.

1.7.4 Health technology developers' perspective

Within current HTA practice, health technology developers are treated primarily as parties being assessed and data suppliers, rather than as collaborators and active participants in shaping the frameworks that govern market access. However, developers are directly affected by HTA outcomes and processes: their investment decisions, evidence strategies and market priorities are shaped by how feasible, transparent, and predictable HTA systems are (Hendriks et al., 2018). If developers perceive existing assessment pathways as misaligned or unviable, they may be disincentivized to enter or stay in a given market, impacting patient access to new health technologies and ultimately the digital health market and innovation ecosystem. From a stakeholder innovation perspective, engaging with beneficiaries, those affected by current methods and dependent on their outcomes, is crucial to ensuring that HTA innovations are not

only methodologically robust but also implementable (Jiu et al., 2022). The insights of technology developers therefore, are thus indispensable in the early phases of method innovation, particularly in identifying barriers and articulating practical needs.

The category of "health technology developers," however, is heterogenous. As outlined in chapter 1.1.1, DHTs can be developed by a wide variety of organisations, ranging from individual software engineers, through tech startups, academic research groups to large medical device manufacturers and pharmaceutical firms. In the European regulatory context, the developer is formally intended to be either a manufacturer[2] or, if the DHT qualifies as an AI system, a provider[3]. This variation in developer profiles significantly shapes how companies perceive, experience, and respond to HTA challenges. For example, organisations with prior experience in pharmaceutical or medical device regulation may be better equipped to anticipate the types of evidence and documentation needed, whereas technology-first firms may encounter steep learning curves and delays when first interacting with HTA systems.

These considerations highlight the importance of better understanding the perspectives of developers in the context of HTA method evolution. Yet, empirical evidence on how this stakeholder group perceives current systems, and how their insights could inform methodological development, remains limited. This underlines the need for further investigation into their role as innovation stakeholders, particularly within the context of emerging HTA frameworks aimed at evaluating DHTs. This dissertation contributes to addressing this gap by capturing developer perspectives and incorporating them into the conceptualisation of a HTA framework for DHTs.

2 Objectives

In the context of the problems outlined above, contributing to a multi-stakeholder HTA innovation program for DHTs, this doctoral research aims to identify key barriers, challenges

[2] According to Regulation (EU) 2019/1020, a manufacturer is defined as "any natural or legal person who manufactures a product or has a product designed or manufactured and markets that product under its name or trademark

[3] Regulation (EU) 2024/1689 specifies that a provider refers to "a natural or legal person, public authority, agency, or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge.

and perceived needs of DHT developers in securing market access and reimbursement for DHTs in the current HTA landscape of Europe. Building on these challenges and needs, this doctoral thesis seeks to offer recommendations for adaptations of HTA processes that acknowledge practical realities and expectations of developers of DHTs. Within this focused problem area, the formulated research questions and corresponding hypothesis proposed are the following:

- **RQ1:** What are current international practices of DHT-specific HTA frameworks in the European region?

  H1: DHT-specific HTA frameworks remain limited across Europe, with significant variation in scope (of DHTs included), methodology (domains assessed) and reimbursement mechanisms in place across countries.
- **RQ2: (a)** What are the key challenges and perceived needs of DHT developers in securing market access and reimbursement? **(b)** Do the challenges vary by technology type and company size?

  H2: (a) Key challenges and perceived needs of DHT developers are closely related to current institutionalisation of DHT evaluation in the region. **(b)** The challenges impact SMEs, including startups disproportionately and vary by type of technology.
- **RQ3:** How can challenges and needs of DHT developers be addressed in context of a DHT-specific HTA framework?

  H3: Adapting the HTA process by closing the gap between challenges of DHT developers and characteristics of digital innovation will shift HTA from being perceived as a barrier to an enabler of innovation by DHT developers.

By addressing the above research questions and examining the guiding hypothesis, the overall aim of this research is to support the future direction of HTA practices framing digital health innovation in the European region. The intention is to improve alignment between HTA processes and digital health innovation, ultimately supporting more predictable, transparent and innovation-friendly access pathways for DHTs and facilitate digital health innovation across Europe.

The research builds on a combination of quantitative and qualitative methods, routed in the identification phase of IHTAM framework (Figure 1), by examining current literature and first-hand examples of how DHT developers perceive current HTA processes, how they imagine the future and formulating recommendations to ensure that HTA remains relevant and usable

in the context of assessing DHTs. By understanding the current landscape, the barriers and needs that technology developers face and considering recommendations for adaptation, the results of this research seek to inform the development of a HTA framework specific for DHTs in wider context of the multi-stakeholder EDiHTA project. The development of the HTA framework is out of the scope of this doctoral research and will take place under the EDiHTA project after aligning the needs of all stakeholders within the digital health ecosystem. *Developer perspectives, examined in this dissertation, will complement insights from other stakeholder groups during the development, including policymakers, HTA bodies, healthcare providers and patients*, contributing to a more inclusive and practically grounded methodological innovation of HTA practices.

Beyond its applied contribution to health policy and HTA practice, this dissertation advances knowledge in the fields of innovation management and health policy. It offers a developer-centred perspective on how HTA can function as part of a broader policy mix, shaping developer behaviour, decision-making and investment decisions when it comes to DHTs. It also takes a multi-level perspective on how the current policy mix needs to evolve and align to enable more predictable, transparent and innovation-friendly, yet evidence-based decision-making in European health systems.

3 Methodology

To address the above research questions, a four-fold qualitative-dominant methodology was employed, combining a scoping review, a survey, focus groups and interviews and a gap analysis. Multi-method research is widely used in studying innovation, as they allow for the exploration of both system-level patterns and individual-level experiences (Edquist, 2006). In the context of health policy and digital transformation, this design is particularly valuable for capturing structural dynamics while also giving voice to key stakeholders (Greenhalgh *et al.*, 2017). A stepwise structure of the research strengthened the consistency of the results and ensured that results were cross validated across stages of the research. Each phase had a particular aim and addressed different research questions and concerns. Moreover, the qualitative phase (focus groups, interviews, gap analysis) depended upon the quantitative phase (literature review, survey). In this sense, the literature review and survey provided contextual information the focus groups, interviews and gap analysis (Brannen, 2005), while during the focus group and interview participants were invited to reflect on the

literature review and survey findings, allowing for validation, contextualisation and deeper exploration of areas of agreement or divergence.

To address RQ1, a scoping literature review (see Chapter 3.1) was conducted to identify and analyse international practices and existing frameworks for assessment of DHTs. This review examined existing pathways dedicated to DHTs to speed up market access and get reimbursed in five national contexts, offering DHT developers alternative pathways to put their solution on the market. Since the field of digital health is growing dynamically several other countries have launched frameworks dedicated to DHTs since the initial literature search, therefore a supplementary literature search was conducted in March 2024. Following the literature review, a survey (see Chapter 3.2) was developed and distributed among DHT developers across Europe to address RQ2: identifying their knowledge of HTA and most critical factors from perspective of HTA in developing and putting DHTs on the market. Survey responses were followed up with focus groups and interviews (see Chapter 3.3) with participating technology developers to validate and get in-depth insights on the findings. Additional technology developers were identified and included in the interview process through a snowball sampling method, based on recommendations from stakeholders already involved. Finally, RQ3 was addressed through an expert workshop and thematic analysis for formulation and analysis of recommendations for new HTA process specific for DHTs (see Chapter 3.4). Recommendations were derived inductively from the challenges and needs identified in prior phases and complemented by developers' visions of an "ideal" HTA process. These recommendations were analysed through the lens of the innovation policy literature, applying the policy mix perspective. In line with H3, this approach framed HTA reforms not merely as methodological adaptations but as policy instruments shaping innovation incentives and market dynamics in the European digital health market.

3.1 Literature Review

To identify and map international practices (RQ1), existing pathways for market access of DHTs that developers could utilise, a scoping literature review was carried out in July 2023. The primary goal of the literature review was to identify existing pathways, national HTA frameworks, methodological approaches and guidelines used specifically for assessing added value of DHTs. Additionally, the literature search collected information on the classification framework and public financing of digital health technologies to get a wider picture of the policy environment DHT developers were experiencing. The literature review was performed

according to the PRISMA-ScR guideline (Tricco *et al.*, 2018), specifying the search strategy, the eligibility criteria, the selection of sources of evidence, and the method of the analysis.

Search strategy

The literature search was carried out in July 2023 on PubMed, Embase and Google Scholar databases using the following keywords: digital health or digital health technologies or digital health technology or digital health application or e-health or ehealth or mhealth or m-health and financing or finance or health technology assessment or reimbursement or public reimbursement or HTA. As the field and related publications are growing dynamically, a supplementary search was executed in May 2024 to include new guidance and emerging HTA frameworks.

Table 1. Search string of the scoping literature review

((digital health[Title]) OR (digital health technologies[Title]) OR (digital health technology[Title]) OR (digital health application[Title]) OR (e-health[Title]) OR (ehealth[Title]) OR (mhealth[Title])OR (m-health[Title])) AND ((financing[Title]) OR (finance[Title])OR (health technology assessment[Title]) OR (reimbursement[Title]) OR (public reimbursement[Title]) OR (hta[Title])) AND (2013:2022[pdat])

Eligibility criteria & selection of sources of evidence

Specific inclusion and exclusion criteria were applied. Peer-reviewed literature, grey literature, official documents and guidelines were included if they were published between 2013 and 2022 (for the initial search) and between 2023 and 2024 (for the supplementary search), written in English, French, German, Spanish or Hungarian and contained information on classification, assessment, evidence standards and/or national-level reimbursement of digital health technologies. The initial literature review had been limited to 5 countries in the European region: Germany, France, Belgium, the United Kingdom and Finland. These countries were considered as pioneering countries in the region at the time of the initial literature review as they have adapted specific methodologies for assessment of DHTs and several publications and reports describing these systems can be identified. For the supplementary literature search scope was widened to additional countries in the European region such as Spain and Scottland.

Due to the nature of the digital health ecosystem, we assumed that key sources regarding the existing HTA frameworks, methodologies and guidance would not be found exclusively in peer-reviewed scientific literature. Therefore, alongside the scoping literature review, a

detailed examination of the grey literature was also conducted. While collecting grey literature, reports and documents prepared by government institutions and agencies, international professional organizations, and academic centres were identified. Exclusion criteria were publications published before 2013, editorials, conference papers, commentaries, abstract only publications, and did not contain specific and relevant information on the assessment of digital health technologies and/or reimbursement of digital health technologies of the countries under review.

Data extraction & analysis

Four reviewers screened the publications identified in the literature search. Working in pairs, the reviewers assessed the title, abstract, and then the full text of potentially relevant publications in the review. In case of disagreement, a third reviewer was involved. Prior to data extraction, publications were organized according to a coding frame with label definitions using a qualitative data analysis software Atlas.ti (ATLAS, 2025). Three macro-level codes were applied: (1) Publication type, such as review article, HTA framework, methodological guideline, regulation, or policy report, (2) Country of application, to classify documents by national context and (3) Primary theme(s): distinguishing whether the literature focused on HTA, reimbursement or classification relating to DHTs. The coding frame was developed iteratively during an initial calibration phase and applied consistently across all included documents to enable structured comparison and synthesis.

Data extraction was performed using standardized tables in Microsoft Excel. The development of the data extraction table was validated through a pilot data extraction, during which data was extracted from 5 publications using the first version of the table. The following data categories were extracted from the publications that were ultimately included in the literature review: (1) General information, including the names of the authors, year of publication, title, type of research, research objectives, research conclusions (if relevant), language of publication, (2) Name of assessment framework or methodology, (3) Country of application, (4) Information on scope of DHTs assessed, including information on type of technology, risk class (if specified), potential users (if specified), disease area (if specified), (5) Information on assessment criteria and requirements, including assessment domains (if any), (6) Information on whether the framework is connected to a public reimbursement pathway. A comparative analysis was conducted across countries to identify differences in institutionalisation, scope

and methodological approach, forming the basis for addressing RQ1 and exploring H1, which hypothesised variable institutionalisation of DHT specific HTA frameworks across Europe.

3.2 Survey

To assess challenges and perceived needs of DHTs (RQ2a) and differences between developers (RQ2b), a questionnaire was created to assess familiarity of DHT developers with the concept of HTA and understand what factors influence their decisions around the development and implementations of a DHTs. Participants were recruited by reaching out to technology developers through conferences and networking events where the EDiHTA consortium was present (e.g. HIMSS Europe 2024) as well as to the EIT Health network[4] and MedTech Europe[5] network through internal staff. The selection criterion for participants was that their companies engage in DHT development and deployment in one or more countries in Europe. The survey was designed using only closed-ended questions, with no qualitative or open-text fields except a final optional comments box. This ensured that responses could be systematically compared and quantified.

For the survey, reliability and validity checks were conducted, including a pilot test before distribution: an initial version of the questionnaire was reviewed by a panel of experts within the EDiHTA consortium, composed of academic researchers with experience in HTA that evaluated the clarity of the questions, their relevance to the study objectives and the comprehensiveness of the domains covered. The questionnaire was tested on a preliminary sample of developers, representative of the target population. The feedback received was used to improve the wording of the questions and ensure consistency in the Likert response scale. The final version of the questionnaire demonstrated a good level of clarity and comprehensibility, and no systematic issues were reported during its completion. The survey (see Appendix A) was structured into two main sections.

The first section (questions A-H) gathered background information about the responding companies, including company name, country of primary market, year of establishment, main therapeutic areas and type of technology developed (e.g., mHealth, telemedicine, AI, robotics).

[4] The EIT Health network includes over 100 leading organisations, exceptional in the worlds of business, education, research and health service delivery (EIT Health, 2025).

[5] The MedTech Europe association includes members from more than 140 multinational corporations and more than 45 medical technology associations (MedTech Europe, 2025).

This information was essential for understanding the diversity of company sizes (e.g., start-ups vs. large companies), diversity in types of technologies (mHealth, telemedicine, AI, robotics) the level of internal capacity for HTA or market planning and the specific therapeutic contexts in which the DHTs operate. This data primarily informed the segmentation of respondents for analysis and interpretation. Respondents were asked to list their technology types in order of priority. We also inquired whether the companies have an internal HTA/ market access department or a person responsible for HTA/ market access within their organisation. This question was essential to understanding the organizational capacity and strategic maturity of DHT developers when it comes to navigating market entry. The presence (or absence) of such departments can be a strong indicator of a company's familiarity with HTA processes and their preparedness to engage with national or regional decision-makers.

The second section of the questionnaire was designed to gain deeper insights into how DHT developers make strategic decisions regarding DHT development and implementation. Respondents were presented with a range of statements and asked to rate the importance or relevance of each factor on a 9-point Likert scale (1 = Not at all important/relevant; 2 = Minimally important/relevant, 3 = Slightly important/relevant; 4 = Somewhat important/relevant; 5 = Moderately important/relevant; 6 = Quite important/relevant; 7 = Very important/relevant; 8 = Highly important/relevant; 9 = Extremely important/relevant). The questions covered themes such as clinical relevance, improvement in clinical outcomes, regulatory complexity, technical characteristics and the technical adaptability of the technology. Several items explored economic considerations, such as development and maintenance costs and expected ROI, as well as factors related to patient safety, stakeholder involvement and data governance, such as privacy, ownership and compliance with GDPR. We asked how important the HTA process in the target market is for development and deployment, and whether developers actively study and analyse HTA procedures prior to making development decisions. These items were essential to identifying whether HTA is used reactively at the point of market entry or proactively during initial design and planning stages. Furthermore, technology developers were asked to share any additional considerations that were important to them when developing a DHT. The aim of this section was to identify the primary drivers of development strategy, as well as to understand how HTA-related processes and market access considerations are embedded in decision-making.

Analysis

Survey responses were exported to Microsoft Excel and analysed using descriptive statistics. For each item rated on the Likert scale, means, medians and ranges and standard deviation (SD) were calculated to capture central tendency and dispersion attributed to each factor. To explore sub-group specific insights, these calculations were performed both across the full sample and by subgroups based on the type of digital health technology developed (e.g. mHealth, telemedicine, AI-based technologies and industry-size companies). This approach aligns with recommended practices for analysing Likert-scale data (Boone and Boone, 2012; Sullivan and Artino, 2013) and allowed for initial comparison of strategic priorities and decision-making patterns across developer types, supporting the examination of H2**,** which hypothesised that smaller or early-stage companies face greater challenges in navigating HTA and reimbursement processes. Group assignment was based on self-declaration of the primary category above. Where respondents selected multiple technology types, the stated priority order was used. If clarification was needed, the respondents were contacted. Overlap across features may persist despite this rule, so comparisons are interpreted cautiously. With these insights, knowledge on the current state of art regarding the developer's perspective of the European market for DHTs was obtained. This knowledge was then used to prepare the interviews and focus groups aimed to validate the results of the literature review and survey.

3.3 Focus Groups & Interviews

Focus groups and interviews were conducted following the initial analysis of the survey responses as the second stage to assess challenges and perceived needs of DHTs (RQ2a) and differences between developers (RQ2b). To allow for comparison across different types of technologies and company perspectives, participants were divided based on company size and technology types for the interviews and focus groups. Participants were scheduled into focus groups that matched their primary category derived from the survey. Two exceptions applied: a mixed group that combined several technology types due to scheduling constraints, and cases where a developer could not attend their intended group and joined another available session. All interviews and focus groups were conducted online to facilitate participation from developers across 10 European countries. Interviews lasted 60 minutes, while focus groups were scheduled for two hours.

A standardized protocol was developed for both focus groups and interviews (see Appendix B) with open-ended questions to guide the sessions. This approach allowed flexibility for discussions to cover various aspects and types of technologies. The protocol was structured

based on the Innovation in Health Technology Assessment (IHTAM) framework (Jiu *et al.*, 2022) which guided participants through a reflective and forward-looking process. The IHTAM model was developed by the HORIZON 2020 HTx project to support the innovation process that is applicable to all types of HTA methods and to illustrate how different HTA stakeholder groups can engage dynamically and collaborate effectively throughout the innovation process (Oortwijn *et al.*, 2022). In the first part of the sessions, participants were asked to "learn from the past and present" by describing the current market access and reimbursement processes and identifying limitations within current HTA systems. In the second part, participants were encouraged to "imagine the future," visualizing an ideal HTA process while identifying potential enablers and barriers for its realization. Once challenges and needs were identified, stakeholders were asked to decide whether existing methods could be improved or if novel methods needed to be developed to address these challenges.

Analysis

Sessions were audio or video recorded to ensure accuracy and comprehensive, participant-specific notes were taken in parallel. Notes were taken specifying what each participant has contributed to the discussion. This allowed for systematic tracking of contributions and ensured the ability to differentiate perspectives by company type (e.g., SMEs, including startups vs. industry-sized) and technology focus (e.g. mHealth, telemedicine, AI). For each session, a synthesis of the notes was sent to participants via email for validation to confirm the accuracy of their statements and, ensuring credibility and transparency of the data.

Following the validation of data collected, a thematic analysis was conducted to identify patterns and recurring issues across the interviews and focus groups. The process followed Braun & Clarke's six-step framework for thematic analysis (2006), combining both inductive and deductive approaches. The first round of coding was conducted inductively to allow themes to emerge from the data. Transcripts and validated notes were reviewed in full and initial codes were assigned to meaningful segments of text. These codes captured both manifest content (e.g., direct challenges cited) and latent content (e.g. underlying needs and assumptions). In the second round, codes were organised deductively according to the structure inspired by the IHTAM framework and the lifecycle of DHTs. Primary thematic clusters were created along the lifecycle of DHTs (regulatory compliance, evidence generation, HTA, reimbursement and implementation), reflecting the temporal progression of challenges and needs across the stages of regulatory compliance, market access, evidence generation, HTA, reimbursement, re-

evaluation and implementation. Secondary codes were applied to distinguish differences across company size and technology type, allowing for comparative analysis and the identification of disproportionate effects on SMEs versus industry, and different type of DHTs.

Following this structured coding process, challenges and needs were finally grouped into six overarching themes that reflect the lifecycle of DHTs: Regulatory compliance and market access, Evidence generation, HTA, Reimbursement and re-assessment. This structure enabled a more nuanced understanding of the developer experience across different contexts, while also responding directly to RQ2a & b and H2a & b. Coding was performed manually, with particular attention given to triangulating findings with the survey data where possible.

3.4 Gap analysis

To formulate recommendations for a DHT-specific HTA framework (RQ3), a structured gap analysis was conducted to identify how current HTA practices diverge from the needs of DHT developers. This analytical stage aimed to move beyond descriptive accounts of challenges and toward the formulation of prescriptive recommendations for HTA reform that are practical, proportionate and innovation oriented. To achieve this, a transparent analytical pathway was defined to systematically link raw qualitative data, identified themes, structural gaps and ultimately recommendation elements. By grounding the analysis in empirical data while incorporating future-oriented perspectives, this method positioned HTA reform not merely as methodological refinement, but as a step toward aligning institutional practices with the dynamics of digital health innovation.

The gap analysis drew on data collected in previous phases, including the survey, interviews, and focus groups with DHT developers. From these sources, the challenges and needs of developers were inductively identified and consolidated. These insights were then enriched through the forward-looking exercise during the focus group and interview phase, in which participants were invited to reflect on what an “ideal” HTA process would look like and to articulate both enablers and barriers for its realisation. The combination of retrospective and prospective perspectives enabled a structured comparison between current HTA practices and potential future scenarios. Within this analysis, a “gap” was operationalised as a recurrent and cross-validated pattern where developer-reported needs, expectations or operational realities appeared misaligned with existing HTA procedures, evidentiary standards, timelines or reimbursement structures. The analysis therefore did not equate individual dissatisfaction with

systemic failure but focused on identifying structural gaps that appeared consistently across participants and data sources.

The analytical processing of qualitative data followed an iterative thematic approach. Interview and focus group transcripts were manually coded in a first cycle using inductive open coding, capturing recurring concepts (e.g. evidentiary burden, regulatory ambiguity, financial constraints, timeline mismatches, scalability barriers, stakeholder misalignment). To ensure consistency and traceability, in the second cycle the resulting recommendation elements were grouped into overarching themes aligned with the lifecycle of DHTs, reflecting the analytical framework applied in earlier phases of the research. This dual structure, inductive coding within a predefined conceptual structure, ensured that themes remained grounded in participant language while analytically consistent with the broader framework guiding the study.

Before formulating recommendation elements, particular attention was given to identifying potential root causes underlying the observed challenges. Where similar concerns emerged across interviews, focus groups, and survey findings, these were interpreted as indicative of systemic rather than isolated issues. This step aimed to ensure that recommendations addressed structural drivers rather than surface-level symptoms. Prioritisation of identified gaps was informed by three criteria: (1) frequency and consistency across data sources, (2) cross-cutting relevance across DHT types and company sizes, and (3) perceived systemic impact on market access and reimbursement pathways. Through this approach, the gap analysis provided a structured pathway from developer-reported challenges to concrete recommendations for a DHT-specific HTA framework. In parallel, relevant academic literature and examples of international good practice were reviewed to support the feasibility, transferability, and scalability of the recommendations.

This structure enabled a more nuanced understanding of how developer-reported challenges translate into practical recommendations for reform, while also responding directly to RQ3 and H3. The gap analysis was conducted manually, with particular attention given to linking challenges and needs identified in earlier phases with forward-looking perspectives from developers. Where possible, findings were triangulated across survey, interview, and focus group data to ensure consistency and robustness of the recommendation elements.

To ensure the transparency of the research presented in the dissertation, Table 2 provides a summary of the proposed hypothesis, related research questions, objectives and methods discussed in previous chapters before presenting the results in detail. Additionally, the table indicates which chapters of the dissertation provide a detailed discussion of the results corresponding to each objective and method.

Table 2. Summary of hypothesis, research questions, objectives, methods and corresponding results presented in the dissertation

	Research Question	**Objective**	**Methodology**	**Hypothesis**	**Results (Chapter)**
1	What are current international practices of DHT-specific HTA frameworks in the European region?	Identify and compare international HTA-based market access pathways for DHTs in the European region	1. Scoping literature review (Jul 2023) and supplementary literature review (March 2024)	H1. DHT-specific HTA practices across Europe remain limited and fragmented, with significant variation in scope (technologies included), methodology (domains assessed) and reimbursement mechanisms across European countries	4.1
2	(a) What are the key challenges and perceived needs of DHT developers in securing market access and reimbursement? (b) Do the challenges vary by technology type and company size?	Assess challenges and perceived needs of DHT developers, segmented by type of DHT and company size	2a. Questionnaire (Jul 2024) 2b. Interviews & Focus Groups (Oct 2024)	H2 (a) Barriers and challenges of DHT developers root from misalignments between current HTA practices and the characteristics of digital innovation. (b)Barriers and challenges impact SMEs disproportionately and vary by type of technology.	4.2
3	How can challenges and needs of DHT developers be addressed in a DHT-specific HTA framework?	Formulate recommendations for DHT-specific HTA that enable innovation based on needs of DHT developers	3a. Gap analysis (March 2025)	H3. Adapting the HTA process by closing the gap between challenges of developers and characteristics of digital innovation will be perceived as an enabler of innovation by DHT developers	4.3

4 Results

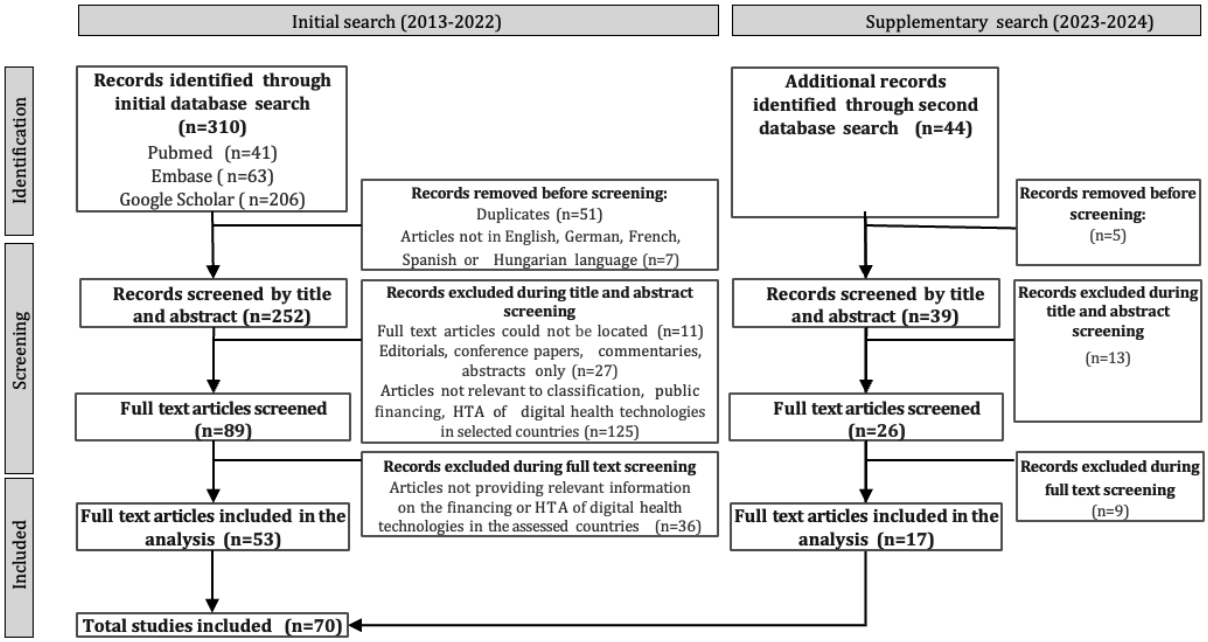
4.1 International practices of DHT-specific HTA

4.1.1 Overview of literature review results

This chapter presents the findings of the literature review conducted to map current HTA and reimbursement frameworks for DHTs in Europe. The analysis is based on a total of 70 included sources, identified through an initial scoping review (n=53) and a supplementary search (n=17), as illustrated in the PRISMA diagram (Figure 2). The first literature search, conducted in July 2023, yielded 310 records. After removing duplicates and ineligible records, 89 full text documents were assessed, of which 53 were included in the final analysis. The second, supplementary search identified an additional 44 records, of which 26 were reviewed in full, and 17 met the inclusion criteria. The studies included in the analysis represent a mix of publication types and national contexts, reflecting the evolving and decentralised nature of digital health policy development across Europe. Most sources fell into five main categories: review articles (n = 33), methodological guidelines (n = 12), HTA frameworks (n = 9), policy reports (n = 7), and regulatory documents (n = 3).

Figure 2. Flowchart of the literature search results

Figure presents results on international practices on public financing and HTA of DHTs for the initial search and supplementary search. Source: based on Mezei et al. (2023)



The primary focus of the analysis was on seven European countries: Germany, France, Belgium, Spain, the United Kingdom (including Scotland), and Finland. Among these, Germany and France were the most frequently represented, with 12 documents each, followed by Finland and Belgium (n = 7 each), and the United Kingdom and Scotland combined (n = 11). Spain was included in three sources that discussed national policy adaptations and HTA reform initiatives. These countries were selected based on their active role in piloting or institutionalising DHT-specific evaluation and reimbursement pathways. In addition to country-specific materials, a subset of sources (n = 17) addressed multiple countries or European-level comparisons. These often provided methodological overviews, policy analyses or conceptual frameworks that contributed to the broader discussion but were not always embedded in national implementation. A smaller number of sources referred to other countries outside the core focus of this research, including the Netherlands, Israel, Hungary and Sweden.

4.1.2 DHT-specific HTA frameworks

The analysis of included literature revealed that seven countries have introduced a total of nine DHT-specific HTA frameworks and/or guidelines for evaluating DHTs (Table 3). In addition to dedicated pathways for DHTs, several countries have introduced AI-specific checklists as an add-on to their HTA processes, however these fall outside of the scope of the research.

Among the DHT-specific HTA frameworks, Germany's DiGA Fast-Track was the earliest comprehensive framework identified, DHTs aiming to increase the adoption of high-quality "DiGAs" ("Digitale GesundheitsAnwendungen") in the German healthcare system. It enables low-risk, patient-facing digital medical devices to be listed in a public directory and reimbursed under statutory health insurance under the German Digital Healthcare Act ("Digitale-Versorgung-Gesetz") (BfArM, 2020), following a structured assessment and evidence submission process. The DiPA Fast-Track, introduced in 2023, expands the regulatory and reimbursement ecosystem developed under the DiGA scheme to digital care applications (Digitale Pflegeanwendungen or "DiPAs"). While DiGAs focus on patient-facing medical applications, DiPAs are intended to support individuals with care needs in the home or in institutional settings. This includes technologies that enhance autonomy, improve communication, or assist with everyday activities, and may be used either independently by care recipients or in coordination with caregivers and nursing staff (BfArM, 2023).

The DiPA Fast-track also allows for the inclusion of non-CE marked technologies under certain conditions and serves a different user group and use context. In addition to launching DiPAs, German health authorities have initiated discussions around expanding the DiGA scheme itself. Proposals include extending eligibility to higher-risk digital medical devices (currently limited to MDR class I and IIa), potentially accommodating class IIb and III solutions. Moreover, the scope may be widened to include non-patient-facing digital tools, such as clinical decision support systems or hospital-level applications aimed at improving operational efficiency or reducing costs (MedTech Europe, 2021). Such developments suggest a gradual institutional evolution towards broader inclusion of digital solutions across the patient pathways, encompassing not only individual self-management apps but also professional- and system-facing technologies.

In France, multiple pathways for are available for technology developers to get digital medical devices (DMDs) ("Dispositifs Médicaux Numériques"; "DMN") reimbursed. Telemedicine DMDs can be registered in the list of remote medical monitoring activities ("Liste des Activités de Télésurveillance Médicale", LATM) (HAS, 2024a). The LATM was introduced after the conclusion of the ETAPES program, a temporary national funding initiative for remote patient monitoring experimentally launched in 2016. LATM formalises reimbursement for telemonitoring activities based on clinical indications, expected benefits, and CE-marked solutions that comply with national standards of interoperability and data protection. In parallel, since 2023, developers can also access early and conditional funding through the "Prise en Charge Anticipée Numérique" pathway (PECAN) (HAS, 2024b), which provides temporary reimbursement for digital medical devices with expected clinical value but limited existing evidence. PECAN evaluations are streamlined with CNEDiMTS, a committee of HAS, assessing presumption of innovation in terms of clinical benefit or progress in the organization of care, based on the first available data, and the Digital Health Agency (ANS) verifying compliance with interoperability and security standards. Together, LATM and PECAN reflect a multi-tiered approach to facilitating HTA evidence generation and structured reimbursement for DHTs within the French health system. A specialized department was created three years ago within HAS to guide digital health technology assessment and support implementation in clinical pathways and hospital certification. The team comprises classic HTA experts, and, when necessary, it incorporates external digital technology specialists to enhance internal expertise.

Belgium's mHealthBelgium framework, first launched in 2019 and revised in 2023, applies a multi-level structure to assess interoperability, technical quality, and added value. The original pyramid model consisted of three progressive levels: M1 for CE-marking verification as a medical device, M2 for demonstrating interoperability with Belgium's national eHealth services, and M3 for evaluating clinical and economic value. The revised framework has been streamlined and more directly linked to reimbursement processes, with a stronger emphasis on evidence generation, cost-effectiveness and multi-stakeholder appraisal (INAMI- RIZIV, 2023). The pathway is supported by the Federal Knowledge Centre for Healthcare (KCE) and the National Institute for Health and Disability Insurance (NIHDI), aiming to guide technology developers through a structured market access and reimbursement process. It reflects Belgium's broader commitment to systematically integrating DMDs ("applications mobiles médicales") into the healthcare system, while also highlighting the evolving demands placed on developers to demonstrate value across multiple dimensions.

In Finland, the Digi-HTA framework was developed by the Finnish Coordinating Center for Health Technology Assessment (FinCCHTA) and the University of Oulu in 2018. The framework covers a wide range of DHTs, including non-medical devices such as digital platforms, as well as DMDs like digital health applications and artificial intelligence algo-rhythms, and has been implemented since the end of 2019. It adopts a "traffic light" classification to support local financing decisions. Although not linked to national reimbursement, the framework aims to inform hospital and municipal procurement by providing structured evaluations of DHTs, including mobile health solutions, telemedicine, robotics as well as AI-based applications (Haverinen *et al.*, 2019). Technologies are assessed across multiple domains such as clinical effectiveness, cost, data security, usability and interoperability. A green rating can facilitate adoption, while yellow or red suggest the need for further evidence or adaptation. Assessment outcomes are published on the FinCCHTA website, remaining valid for three years.

In the United Kingdom, the National Institute for Health and Care Excellence (NICE) introduced the Evidence Standards Framework (ESF) to guide the evaluation of digital health technologies in 2019 (NICE, 2022). It serves as a reference for evaluators and decision-makers, such as those involved in identifying, evaluating, funding, or reviewing DHTs, and for companies that develop or distribute these technologies. The ESF adopts a classification system for technologies that differentiates evidence requirements based on the technology's intended

function and potential impact on the healthcare system. It distinguishes three levels: Tier A includes system-level tools with minimal patient interaction (e.g. administrative apps), Tier B covers health management technologies such as symptom checkers and lifestyle apps, and Tier C comprises digital medical devices that support clinical decisions or deliver treatment. The latter are required to meet the most stringent evidence criteria, including robust clinical and economic validation. First released in March 2019, the ESF has undergone several updates: in April 2021, based on user feedback, and in August 2022, to incorporate standards for artificial intelligence (AI) and data-driven technologies with adaptive algorithms. While the ESF does not function as a formal reimbursement mechanism, it is increasingly used by NHS commissioners and procurement bodies to inform adoption and investment decisions.

Table 3. List of DHT-specific HTA frameworks

DHT-specific HTA frameworks identified through the literature review, types of technologies assessed, methodology (domains assessed) and connection to national level reimbursement pathways

Country	DHT-specific assessment framework	Types of technologies assessed	Criteria assessed	National level reimbursement
Belgium	mHealthBelgium	Mobile applications and web platforms CE-marked as a medical device	(1) technical aspects (2) scientific aspects (3) economic aspects (4) temporary refund	yes
Finland	Digi-HTA	Mobile applications, telemedical solutions, AI-based technologies, robotics	(1) Product information (2) Technical stability (3) Cost (4) Effectiveness (5) Clinical safety (6) Data security and protection (7) Usability and accessibility (8) Interoperability (9) Patient and organizational considerations	no
France	Liste des Activités de Télésurveillance Médicale (LATM)	Telemonitoring, telemedicine solutions	(1) Indication(s) claimed (2) Proposed reference framework (3) Demonstrating the expected benefits of remote medical monitoring for medical services (4) Target population	yes
France	Prise en Charge Anticipée Numérique (PECAN) pathway	Digital Medical Devices (DMD) that are CE-marked	(1) Indication(s) claimed (2) Disease concerned (3) Target population (4) Description of digital medical device (5) Description of organisational aspects associated with using digital medical devices for therapeutic use (6) Case of a digital medical device for remote medical monitoring: proposal for a	yes

			reference framework for remote medical monitoring	
Germany	DiGA-Fasttrack according to the Digitale Versongung Gesezt (DVG)	Patient-facing mobile applications and web-based platforms that are CE-marked and MDR risk class I or IIa, IIb	(1) General requirements (data protection, safety and suitability for use, information security, interoperability, further quality requirements) (2) Positive healthcare effect (medical benefit, patient-relevant improvement of structure and processes)	yes
Germany	DiPA-Fasttrack according to the Digitale Pflegeanwendungen-Verordung (DiPAV)	Mobile applications and web-based platforms used in a home care context, non-CE marked or CE marked. If CE marked, it needs to belong in MDR risk class I or IIa	(1) General requirements (data protection, safety and suitability for use, information security, interoperability, further quality requirements) (2) Positive care-related benefits and/or positive impact on illness- or therapy-related demands and strains	yes
United Kingdom	Evidence Standards Framework (ESF) for Digital Health Technologies	DHTs (mobile applications, standalone software, online tools, programmes, classified into tiers A, B, C based on potential risk to users and the system)	(1) Design factors (2) Describing values (3) Demonstrating performance (4) Delivering value (5) Deployment considerations	no
Scottland	Evidence framework for the assessment of health technologies	Clinician- or patient-facing DHTs, including mobile applications, MedTech and devices with an associated app, systems, web-based portals	(1) Technology and its value (2) Safety, acceptability and credibility (3) Performance of the technology (4) Cost and value for money of the technology (5) Digital Technology Assessment Criteria (clinical safety, data protection, technical assurance, interoperability, usability and accessibility)	no
Spain	Digital Health Innovation Assessment Framework	Mobile applications, telemedical solutions, AI-based technologies, integrated DHT platforms	(1) Description of health problem (2) Description of technology (3) Content (4) Safety (5) Clinical efficacy and effectiveness (6) Economic aspects (7) Sociocultural aspects (8) Ethical aspects (9) Legal and regulatory aspects (10) Organisational aspects (11) Technical aspects (12) Environmental aspects (13) Post-deployment monitoring	no

In Spain, the Agency for Health Quality and Assessment of Catalonia (AQuAS) has developed a structured framework for evaluating digital health technologies within the context of the Catalan healthcare system (Segur-Ferrer *et al.*, 2024). The methodology is based on the EUnetHTA Core Model but has been adapted specifically for digital health, incorporating domains that reflect both traditional HTA perspectives and digital-specific considerations. The framework includes thirteen assessment areas, covering technical, clinical, economic, ethical, organisational, and environmental aspects, as well as post-deployment monitoring. While the AQuAS model is not formally linked to national reimbursement mechanisms, it serves as a prototype for structured evaluation in decentralised health systems and has informed broader national-level discussions through its integration into the Spanish RedETS network. The framework exemplifies a regional effort to develop proportionate, transparent, and technology-adapted HTA processes that can support informed procurement and adoption decisions for DHTs.

In Scotland, DHTs are assessed through the traditional HTA framework developed under the Health Technology Assessment (HTA) directorate of Healthcare Improvement Scotland (HIS). While core HTA domains (e.g. clinical effectiveness, safety, cost-effectiveness, ethical considerations, etc.) remain consistent across all medical technologies, an additional domain is incorporated for DHTs. This includes criteria derived from the Digital Technology Assessment Criteria (DTAC) framework, which covers aspects such as clinical safety, data protection, technical assurance, interoperability, and usability (SHTG, 2023). This supplementary digital domain ensures that unique attributes and risks of DHTs, such as cybersecurity vulnerabilities or integration challenges, are not overlooked. Although the framework is primarily advisory and used to support procurement and local decision-making rather than reimbursement, it provides a structured approach to ensure digital tools are safe, effective, and fit for the NHS Scotland context.

4.1.3 Scope of assessment: Types of DHTs covered

The DHT-specific HTA frameworks identified in the literature review reflect considerable variation in the types of DHTs they are designed to assess. All frameworks establish links with the EU MDR, the majority requiring a valid CE mark as a prerequisite for eligibility. However, partial differences in risk levels and functionalities exist among the programs concerning the DHTs of interest. The definition of DHTs as a collective term (e.g. digital health, telehealth, eHealth, mHealth, AI solutions) differs globally (see Chapter 1.2), and the countries use

different nomenclature as well. The examined HTA frameworks apply varying terminology to describe their targeted DHT ranging from “Digitale Gesundheitsanwendungen” (Germany), “applications mobiles médicales” (Belgium), “digital medical devices” (France, PECAN) to broader categories such as “digital health technologies” (UK, Finland) or “health technologies with digital components” (Scotland). This inconsistency in naming reflects national differences in classification systems but also reveals uncertainty around what constitutes a DHT in the policy context.

In addition to inconsistent terminology, the reviewed frameworks vary in terms of which types of DHTs are included, the risk class of eligible DHTs, and the stage of technological maturity at which evaluation takes place. Some frameworks apply strictly to CE-marked digital medical devices, such as Germany’s DiGA (limited to MDR class I, IIa and IIb), Belgium’s mHealth framework, but differ in whether they include mobile apps, web-based platforms or remote monitoring tools. Germany’s DiPA Fast-Track allows the inclusion of non-CE-marked digital nursing applications used in a home care context, if they meet functional criteria and reduce care-related burdens. Similarly, France’s PECAN, is intentionally broader, allowing even higher-risk technologies (MDR risk class III) to enter under conditional reimbursement, including those not yet CE-marked if sufficient early evidence is available. Others, Finland’s Digi-HTA and Spain’s AQuAS framework take a more inclusive approach by assessing AI-driven systems, robotics, telemedicine and integrated care platforms, even in the absence of full regulatory clearance. This suggests a difference in whether HTA is used as a gatekeeper for reimbursement or as a tool to guide procurement and investment readiness.

Another source of divergence lies in the intended context of use and the actor responsible for adopting the DHT. Some frameworks focus on patient-facing solutions (e.g. DiGA until recently). The DiGA model originally included only patient-centred DMDs of risk class I or IIa (as per the EU MDR) whose main function is based on a digital technology. However, with the introduction of the new Digital Act (DigiG) in March 2024, the definition of DiGA has been broadened to also encompass risk class IIb DiGAs (Bundestag, 2024) and is now offering expansion of the DiGA pathway towards additional applications, such as telemonitoring tools. Other frameworks explicitly allow for assessment of clinician-facing tools, clinical decision support systems, or system-level applications such as triage, scheduling or virtual wards (e.g. LATM, PECAN, ESF, Digi-HTA).

While all reviewed initiatives aim to adapt assessment processes to the unique characteristics of digital solutions, there is no common classification system or pan-European consensus on which types of technologies fall under DHT-specific evaluation pathways. This variation underlines the absence of a harmonised definition and classification of DHTs across European countries, a challenge also highlighted in recent academic work (Mezei *et al.*, 2023; Van Kessel, Srivastava, *et al.*, 2023; Tarricone *et al.*, 2024; Zrubka *et al.*, 2024; Boers *et al.*, 2025). These findings confirm H1 by illustrating that DHT-specific HTA frameworks show significant variation in scope (technologies included) across European countries.

4.1.4 Criteria for evaluating DHTs

The comparative analysis of national HTA frameworks reveals variety in the domains used to assess DHTs. The frameworks reviewed build on core HTA domains traditionally applied to pharmaceuticals and medical devices, while introducing additional criteria and assessment domains that capture the distinct features and risks of DHTs. These include aspects like data governance, user interaction, interoperability and technical stability, which are rarely considered in HTA of pharmaceuticals and medical devices but are essential for the safe and effective integration of DHTs into health systems.

Across the nine reviewed HTA frameworks, common criteria assessed are clinical aspects, data protection and usability. While all reviewed frameworks include at least some dimensions aligned with the EUnetHTA Core Model, such as clinical effectiveness, safety and economic aspects, several incorporate additional criteria tailored to the digital context. Notably, usability, data security, and interoperability are included as discrete assessment domains in six of the nine frameworks (e.g. DiGA, DiPA, Digi-HTA, AQuAS, Scotland, and PECAN), signalling a growing institutional awareness of the technical and user-facing complexities associated with DHTs.

The frameworks vary considerably in their comprehensiveness. The most extensive framework is Spain's AQuAS model that includes 13 assessment domains, covering clinical and economic value, but also sociocultural, organisational, legal, and environmental considerations. Finland's Digi-HTA and Scotland's DTAC also take a multidimensional view, including organisational readiness and technical stability. mHealthBelgium or France's LATM focus on essential technical validation and clinical benefits, with fewer provisions for broader system or implementation factors. This suggests that frameworks differ not only in their extensiveness

but also in the underlying goals they pursue. Some act as tools for early validation and access, others as comprehensive instruments guiding procurement or national reimbursement.

The distinction in included DHTs (discussed in Chapter 4.1.2) shapes both the scope of evaluation and the criteria selected to assess them. Framework focusing on patient-facing technologies (e.g. DiGA) or including wellness apps (e.g. Digi-HTA) may put emphasis usability, adherence, trust and PREMs /PROMs. Frameworks that are evaluating tools used in clinical workflows tend to include technical integration, interoperability and clinical safety as assessment domains requirements. Scotland's framework or Digi-HTA, also specify organisational readiness, technical stability or health system context as assessment domains, highlighting that HTA is not only about the technology assessed, but also the feasibility of its implementation.

The majority of frameworks adapt a tiered approach to evidence requirements based on the intended use and or risk class of DHT assessed. The United Kingdom's ESF is notable for its clear guidance on what constitutes acceptable evidence at each tier (Tier A, B and C), including specific expectations around study design, outcome measures and target population characteristics. As the tier (and level of clinical risk) increases, the robustness of the evidence requirements increases too, specifically regarding clinical effectiveness, economic value and real-world performance. The tiered assessments enable proportionate evaluation, ensuring that resource-intensive evidence generation is only required where patient safety and system impact justify it. Other countries, e.g. Germany's DiGA pathway allows provisional listing with 12-18 months to provide required evidence, France's PECAN can also admit DMDs under conditional access with 12 months deadline for evidence provision, while Finland's Digi-HTA also allows adjustment in evidence requirements based on the solution's maturity and intended use.

This comparative assessment confirms that while all reviewed countries aim to evaluate the added value of digital technologies, the criteria they apply differs in scope, terminology and level of detail. This diversity reflects varying national capacities, priorities and policy maturity, but also exposes the fragmentation of assessment approaches across Europe. Frameworks differ in how they interpret the relevance of technical and system-level factors, and in how they operationalise evidence expectations for DHTs with varying risk levels and user contexts.

These findings confirm H1 by illustrating that DHT-specific HTA frameworks show significant variation in methodology (domains assessed) across European countries.

4.1.5 National level reimbursement

National level reimbursement mechanisms for DHTs differ substantially across European countries, both in terms of eligibility criteria and funding pathways. Three countries out of the seven reviewed have fully institutionalised fast-track processes linked to national level public financing (e.g. Germany, Belgium, France), others remain in earlier stages of development, limiting reimbursement to pilot settings or decentralised decisions (e.g. Finland, Spain, UK, Scotland). Germany and France introduced preliminary listing or conditional reimbursement mechanisms to support earlier access to promising DHTs, reflecting that conventional reimbursement models may not align with the innovation cycles and evidence timelines of DHTs.

In Germany, the DiGA Fast-Track allows CE-marked, low- to moderate-risk digital medical devices (class I, IIa, and IIb) to be preliminarily listed in the national DiGA directory if they meet general requirements (e.g. data protection, usability, interoperability) and present a plan for demonstrating a "positive healthcare effect". This preliminary listing, valid for up to 12 months (extendable to 24), permits manufacturers to receive public reimbursement while collecting real-world evidence to support permanent inclusion. From January 2026, a performance-based pricing component will become mandatory for DiGAs, requiring anonymised usage data and patient-reported outcomes to account for at least 20% of the reimbursed price, further institutionalising outcome-based payment models (Bundestag, 2024).

France's PECAN preliminary listing model was inspired by the DiGA but takes a broader and more flexible approach. It allows early and temporary reimbursement for digital medical devices that are not yet CE-marked particularly higher-risk solutions (class IIb and III), provided they demonstrate promising early evidence and address unmet clinical needs. PECAN offers one-year temporary coverage for innovative DHTs with yet unproven clinical or organizational benefits. During temporary reimbursement, CNEDiMTS must check that the studies in progress are well designed to provide sufficient data within the timeframe required for the "classic" HTA pathway. Following CNEDiMTS's findings, the Ministry of Health and Social Security confirm early reimbursement eligibility. PECAN provides temporary, non-renewable reimbursement, and manufacturers have up to 6 months (DMDs) or 9 months

(telemedicine DHTs) to apply for standard reimbursement afterward. The aim is to support earlier access to innovative tools while encouraging real-world data collection to inform long-term reimbursement decisions.

To access public reimbursement in Belgium, DHTs must reach M3, the highest level of the mHealth platform, which requires demonstrating both therapeutic added value and technical interoperability with national health system infrastructure, particularly the eHealth platform and hospital information systems. The National Institute for Health and Disability Insurance (INAMI/RIZI) plays a central role in assessing therapeutic value and determining reimbursement eligibility, based on the dossier submitted by the manufacturer and reviewed by the internal expert committee. Unlike Germany's DiGA or France's PECAN, Belgium's model does not currently include a structured outcome-based reimbursement component. However, by linking reimbursement to CE marking, technical compliance, and system integration, mHealthBelgium serves as a gatekeeper model, streamlining access for mature and technically aligned solutions. As of 2024, the platform is increasingly used as a reference for national public and hospital-level procurement, providing a de facto national validation even for solutions not yet reimbursed through public insurance.

Finland uses the Digi-HTA framework to guide local and regional procurement decisions at the hospital district level, particularly within the joint municipal authorities that manage specialised care. Similarly, Spain's AQuAS framework is used to inform regional health authorities, especially in Catalonia, on whether DHTs should be integrated into service provision. Evaluations are conducted within decentralised regional HTA bodies and used to support public procurement or pilot-based rollouts. The ESF is not linked to national reimbursement via NHA England. Decisions on funding and adoption in the UK are made by local NHS trusts, integrated care systems (ICSs), or commissioning groups, often influenced by pilot evaluations, innovation funds (e.g., Accelerated Access Collaborative), or real-world evidence initiatives. A similar approach is used in Scotland, where the Scottish Health Technologies Group (SHTG) applies a broader HTA model with DHT-specific extensions. Here, the Digital Health and Care Directorate supports innovation in partnership with NHS boards, but reimbursement or integration into care occurs via local procurement or pilot implementation such as the Technology Enabled Care (TEC) Programme (Scottish Government, 2018).

Across Finland, Spain, the UK, and Scotland, the absence of a centralised reimbursement mechanism reflects a decentralised approach to integrating DHTs into public systems. Instead of HTA-linked reimbursement decisions, these countries rely on local procurement, pilot studies and innovation funding to introduce digital tools into clinical practice. While these models foster regional and local flexibility, the lack of national reimbursement linkage may limit scalability and create uneven access across regions. These fragmented approaches contrast with the more centralised and outcome-driven reimbursement pathways seen in Germany, France, or Belgium, and further underline the institutional variation in how Europe is approaching the integration of digital medical technologies into publicly funded healthcare.

4.2 Challenges and perceived needs of technology developers

4.2.1 Results of survey

4.2.1.1 Overview of participants

The survey was completed by 23 technology developers, with three incomplete responses that were excluded from the analysis. Responses were deemed incomplete if the respondent only completed part 1) General information of the survey, leaving part 2) Information regarding market access & reimbursement strategies empty. Out of the 20 technology developers with complete answers, six were categorised as mobile app developers, four as telemedicine developers and five as AI developers. The remaining five developers were large industry representatives and/or part of MedTech Europe. Participants can be best understood as an information-rich, lead-user group rather than a representative cross-section of all European developers, but the sample can be considered a good representation of thought-leader DHT developers in Europe. Sampling also aligns with the lead-user logic, where stakeholder with the strongest stakes engage early in desired change and surface emerging needs and barriers (von Hippel, 1986).

The majority of respondents (n=12/20) reported having a dedicated department or expert for evaluation, market access or HTA within their organizations (Figure 3a). This included almost all large industry players (n=4/5) and seven of the 15 SMEs/start-ups. By technology type, half of the mobile app developers (n=3/6) and three of the four telemedicine companies reported having dedicated market access capacity. Only two of the five AI developers reported having such a department, suggesting more limited institutional resources among AI developers. Most respondents (n=16/20) indicated that they actively investigate the HTA process in their target markets prior to making development decisions (Figure 3b). This included almost all industry

actors (n=4/5), mobile app (n=5/6), telemedicine (n=3/4) and AI (n=4/5) developers. These figures suggest a generally high level of awareness of HTA expectations among developers, though not always matched with in-house capacity to address them. These results suggest that while most developers are aware of and study the HTA landscape relevant to their product, the extent to which they can act on this knowledge varies.

Figure 3a) Respondents having a department dedicated to evaluation, market access, or HTA within their organization. Figure 3b) Respondents investigating the HTA process of the target market before making a development decision

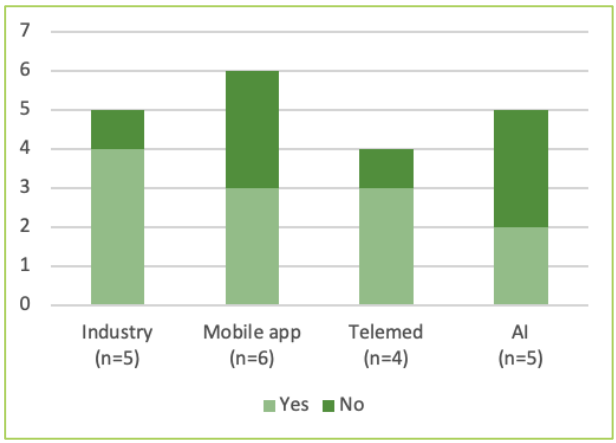


Figure 3a

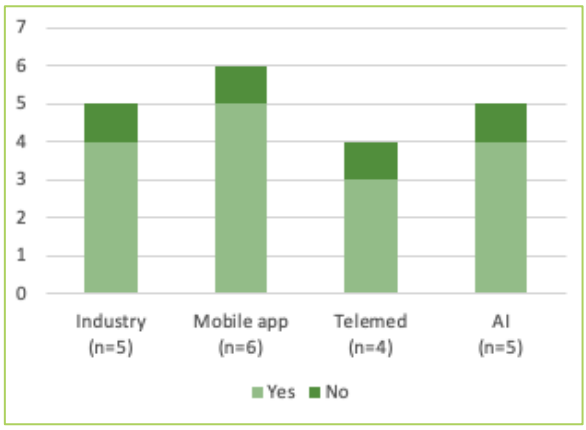


Figure 3b

4.2.1.2 Considerations regarding development and implementation of DHTs

Among general aspects, clinical need and target population was consistently rated highly across all developer groups, with a median of 9 reported for mobile app and industry developers, and 8 for telemedicine and AI developers. This suggests that aligning innovations with a clearly defined clinical indication remains foundational across all DHT types. Regulatory compliance requirements were also rated highly (median 9 in telemedicine and industry, 8 in AI, and 7,5 in mobile apps), reflecting the continued relevance of navigating MDR and CE-marking standards in early development phases. Complexity and time required to develop the technology showed more varied importance, with a median of 8,5 among mobile app developers, but only 7 across telemedicine and AI groups. Standard of care comparator (SoC) scored a median of 9 among industry representatives but only 7 or 8 in other groups, highlighting that established firms may place more emphasis on aligning with existing clinical benchmarks.

Adaptability in use phase received consistently high median ratings (ranging from 8,5 to 9), while adaptability in development phase showed greater variability (ranging from 6,5 to 8), indicating differences in how early-stage flexibility is valued across DHT types. Telemedicine and industry

developers appeared to prioritise adaptability during development slightly more than mobile app or AI groups.

Across cost-related aspects, initial hardware maintenance was rated lowest (median ranging from 1 to 4,5), suggesting that this factor plays a limited role in strategic decisions in market access, particularly for mobile app and AI developers where products are primarily software-based. In contrast, initial software development and bug maintenance was rated highly across all groups (median 7–8), highlighting its centrality to both early development and post-launch support. Initial personnel needs were given a moderate to high importance across developers, with medians ranging from 6 (telemedicine) to 8 (AI). Other initial costs were rated particularly high for mobile app developers (median 7,5) but considered less critical by telemedicine and AI companies (median 3,5). Ongoing device/hardware maintenance was a moderately relevant concern for telemedicine developers (median 6), reflecting their reliance on physical infrastructure like sensors, devices or larger IoT infrastructures. Mobile apps (median 3,5) and AI (median 1) developers ranked this low, consistent with their software-heavy product models. Ongoing software maintenance received consistently moderate scores across groups, with all medians between 6 and 7. It suggests broad consensus that keeping software functional, up-to-date, and secure is a central concern throughout the product life cycle. Ongoing personnel needs also received moderate to high importance (median 6,5–9), with AI developers assigning the highest rating (median 9), likely due to the specialised expertise required for operating and using these technologies. Other ongoing maintenance costs showed the largest divergence across technologies. Telemedicine developers rated it highest (median 8), possibly due to factors such as cloud storage, cybersecurity infrastructure or third-party platform management. AI developers reported it as least relevant (median 1), indicating that such costs may be either less visible or included into wider operational costs.

Regarding clinical outcomes, direct clinical impact scored highly among mobile app and telemedicine developers (median 9 and 8,5), but somewhat lower among AI developers (8) and industry (8,5), suggesting differential emphasis on measurable health benefits depending on the type of technology. Integration of care was rated most highly by AI and telemedicine developers (median 9 and 8,5), supporting the notion that these solutions often target interoperability within broader health system workflows.

Across all technology types, aspects related to market access and reimbursement were rated as highly relevant considerations during development. Market access consistently received high median ratings (ranging from 8 to 9), suggesting that developers across the board place strong emphasis on achieving entry into health systems. AI developers and industry respondents rated market access at the upper end (median 9), indicating that strategic integration into healthcare pathways is central to their development goals. Mobile app developers rated HTA relevance the highest (median 7,5), while industry stakeholders gave the lowest score (median 7). This suggests that for mHealth startups and SMEs, navigating HTA requirements may represent a more critical and challenging step in the market access process. The importance of reimbursement and market access policies also varied slightly, with AI developers reporting a lower median of 7, compared to 9 for mobile app developers and 8,5 for industry. This discrepancy could indicate that AI developers experience greater uncertainty around funding pathways. Expected ROI was one of the highest-rated items overall across all developers groups, with median values of 8 or higher, except for telemedicine developers, who rated it at 6,5. This suggests that developers place high importance on financial sustainability and scalability when developing and implementing DHTs.

Aspects related to the readiness of health systems and patient populations were consistently rated as highly important across all developer groups. Health system readiness received a median score of 8 across all types, with particularly high values among telemedicine and industry respondents, suggesting a shared recognition that institutional preparedness, (e.g. infrastructure and workflow integration) is essential for successful implementation. Patient-facing dimensions were prioritised even more strongly. Usability and acceptance/willingness to use both received a median of 9 for mobile app developers and 8 or above across all other groups, highlighting a universal emphasis on user-centric design. Expected adherence was also rated highly (median 8 overall), although telemedicine developers reported a slightly lower median of 6, reflecting potential concerns around sustained patient engagement in remote care settings. While early involvement of patients/caregivers showed slightly more variation (medians 7 to 8), early involvement of clinicians and HCPs was consistently prioritised, with a median of 9 across most subgroups. These findings confirm that readiness of both systems and users is central to development strategies, with mobile app respondents placing more emphasis on usability and clinical involvement, while telemedicine developers more focused on structural system factors.

Data-related factors were consistently rated among the highest priorities by developers across all technology types. Privacy and security of the end user received a median score of 9 across all

subgroups except telemedicine (7,5), underscoring a widespread commitment to safeguarding personal data, also a critical consideration under the EU's regulatory framework. Data privacy concerns, including GDPR compliance, followed a similar pattern, with median ratings of 9 across mobile app, AI, and industry developers, and slightly lower for telemedicine (7). Data ownership was also highly valued (overall median 9), but notably lower among telemedicine developers (5,5), indicating that concerns over data control may be less pressing in telemonitoring technologies, possibly due to reliance on institutional health records or predefined data-sharing protocols. In contrast, mobile app developers rated all three domains uniformly high, reflecting the personal and decentralised nature of the data they manage. These results affirm that across DHTs, strong data governance remains a foundational pillar of responsible product development, though specific emphases vary slightly by technology type.

Table 4. Results of survey: Developer considerations regarding development and implementation of DHTs.
Likert-scale scores to question "how important is [below factor] in your decision to develop and implement a DHT on a scale of 1 to 9?" (based on Mezei et al., 2025)

Aspects		**Mobile App** n = 6		**Telemed** n = 4		**AI** n = 5		**Industry** n=5		**All** n = 20	
		mean	median (range)	mean	median (range)	mean	median (range)	mean	median (range)	mean	median (range)
General Aspects	Clinical need and target population	8,4	9 (6-9)	8,0	8 (7-9)	7,6	8 (6-9)	8,8	9 (7-9)	8,2	9 (6-9)
	Size of the target population	7,8	9 (5-9)	7,5	7,5 (6-9)	7,2	8 (5-8)	7,2	7 (5-9)	7,5	8 (5-9)
	Regulatory compliance requirements	7,4	7,5 (5-9)	8,8	9 (8-9)	8,0	8 (6-9)	9	9 (9-9)	8,2	8 (5-9)
	Complexity and time required	8,2	8,5 (5-9)	7,0	7 (5-9)	7,0	7 (5-9)	7,4	7 (4-9)	7,4	7,5 (4-9)
	Clear standard of care (SoC) comparator	8,4	8,5 (5-9)	7,0	7,5 (5-8)	7,3	8 (4-9)	8,4	9 (6-9)	7,6	8 (4-9)
Adaptability	Adaptability of the technology: Initially	8,2	8 (5-9)	7,0	6,5 (6-9)	7,2	7 (6-8)	7,8	8 (7-9)	7,4	7 (6-9)
	Adaptability in the development phase	7,0	6,5 (4-9)	7,8	7,5 (7-9)	7,2	8 (4-9)	7,8	8 (5-9)	7,3	7,5 (4-9)
	Adaptability in the use phase	7,8	8,5 (4-9)	8,5	8,5 (8-9)	8,0	9 (4-9)	9	9 (9-9)	8,3	9 (4-9)
Costs	Initial hardware maintenance (shipping cost, spare parts)	2,4	1 (1-7)	4,3	4,5 (1-7)	2,6	1 (1-5)	3,4	2 (1-7)	3,4	2 (1-7)
	Initial software development/bug maintenance	7,2	8 (4-8)	7,0	7 (5-9)	7,0	7 (5-9)	7,2	7 (5-9)	7,2	7 (4-9)
	Initial personnel needs (quantity and training)	7,4	7 (1-9)	6,5	6 (5-9)	7,6	8 (5-9)	7	7 (5-9)	6,8	7 (5-9)
	Other initial costs	7,5	7,5 (1-9)	3,5	3,5 (1-6)	3,5	3,5 (1-6)	6,5	6 (5-9)	5,5	6 (1-9)
	Ongoing device/hardware maintenance	4,4	3,5 (1-7)	5,0	6 (1-7)	2,6	1 (1-5)	5,1	6 (2-9)	4,1	5 (1-7)
	Ongoing software development/bug maintenance	6,4	6,5 (5-9)	6,5	6 (6-8)	6,4	7 (4-9)	6,6	6 (5-9)	6,6	6 (4-9)

	Ongoing personnel needs	7,2	6,5 (1-9)	7,3	7,5 (6-8)	7,2	9 (4-9)	6,8	7 (5-9)	6,8	7 (4-9)
	Other ongoing maintenance costs	7,0	6 (1-8)	8,0	8 (8)	2,7	1 (1-6)	5,1	6 (1-9)	5,1	6 (1-9)
Clinical outcomes	Direct impact on clinical outcomes	8,0	9 (4-9)	8,0	8,5 (6-9)	6,6	8 (1-9)	7,7	8.5 (6-9)	7,7	8,5 (1-9)
	Integration of care	7,6	8 (1-9)	8,3	8,5 (7-9)	8,2	9 (6-9)	7,6	9 (4-9)	7,6	9 (4-9)
	Continuity of care (long-term)	7,0	6,5 (1-9)	7,5	7 (7-9)	6,2	6 (3-9)	6,8	7 (4-9)	6,8	7 (3-9)
	Type of clinical improvement evidence	7,3	7 (1-9)	7,0	6,5 (6-9)	7,4	8 (5-9)	7,2	8 (6-9)	7,2	8 (4-9)
Market access, Reimbursement	Market access	7,4	8 (3-9)	7,8	8,5 (5-9)	7,6	9 (5-9)	7,7	9 (6-9)	7,7	9 (3-9)
	Health Technology Assessment process	7,8	7,5 (6-9)	7,3	7,5 (6-8)	7,4	7 (6-9)	7,2	7 (2-9)	7,2	7 (2-9)
	Reimbursement and market access policies	7,6	9 (3-9)	7,5	8 (5-9)	7,0	7 (4-9)	7,7	8.5 (7-9)	7,7	8,5 (3-9)
	Expected return on investment (ROI)	8,0	9 (5-9)	6,5	6,5 (6-7)	8,4	8 (8-9)	8,1	8.5 (5-9)	8,1	8,5 (5-9)
Readiness of health system, target population	Readiness of health systems	7,6	9 (4-9)	7,8	7,5 (7-9)	7,6	8 (7-8)	7,7	8 (4-9)	7,7	8 (4-9)
	Readiness of patients: Usability	8,6	9 (7-9)	8,0	8,5 (6-9)	8,0	9 (6-9)	8,2	9 (6-9)	8,2	9 (6-9)
	Readiness of patients: Acceptance, willingness to use	8,4	9 (7-9)	7,5	7,5 (6-9)	8,0	8 (7-9)	8,1	8 (7-9)	8,1	8 (6-9)
	Readiness of patients: Expected adherence	8,6	9 (8-9)	6,8	6 (6-9)	7,8	8 (7-9)	7,9	8 (6-9)	7,9	8 (6-9)
	Early involvement of patients/caregivers	7,8	7,5 (6-9)	7,0	7 (6-8)	7,8	8 (6-9)	7,6	8 (6-9)	7,6	8 (5-9)
	Early involvement of clinicians/HCPs	8,4	9 (6-9)	7,5	7,5 (6-9)	7,4	9 (3-9)	8	9 (6-9)	8,0	9 (3-9)
Data aspects	Privacy and security of the end user	8,4	9 (7-9)	7,3	7,5 (6-8)	8,4	9 (7-9)	8,4	9 (7-9)	8,4	9 (6-9)
	Data ownership	8,6	9 (7-9)	5,8	5,5 (5-7)	7,8	9 (6-9)	7,9	9 (6-9)	7,9	9 (6-9)
	Data privacy concerns (e.g GDPR compliance)	8,6	9 (8-9)	7,3	7 (7-8)	8,2	9 (6-9)	8,4	9 (6-9)	8,4	9 (6-9)

Overall, *developers consistently prioritise clinical relevance, regulatory alignment and data protection* when making decisions about DHT development. Aspects such as *clinical need, regulatory compliance, usability and GDPR-related concerns received the highest median scores across all developer groups,* suggesting that developers are aware of the requirements for safe, effective and acceptable and sustainable implementation of DHTs. However, the analysis also shows that developer priorities may differ depending on the type of technology. This supports the assumption that *developers working on different types of DHTs face different challenges and prioritise different factors, suggesting that HTA and reimbursement frameworks should better account for this diversity*. The survey results also served as a starting point for the interviews and focus groups, helping to validate and deepen the findings in the next phase of the research.

4.2.2 Results of focus groups & interviews

4.2.2.1 Overview of participants

The qualitative phase included 29 participants from DHT development organisations who took part in semi-structured interviews and moderated focus group discussions between September 2024 and November 2024. Four companies involved in the survey did not take part in the interview phase due to scheduling issues, resulting in partial but meaningful overlap between the two data sources. In parallel, six additional companies were recruited for the interviews through snowball sampling, even if they had not completed the survey for various reasons (e.g. lack of time). In total, this study captured input from 31 unique digital health companies across Europe (Table 5). The sessions were designed to reflect the diversity of the DHT landscape, both in terms of company size and technological focus. Participants were developers of mobile applications, telemedicine and telemonitoring platforms, AI-based tools. The sample consisted primarily of SMEs, including startups, with founding years ranging from 2015 to 2021. Several participants represented large multinational firms or corporate alliances some of which have operated globally since the 19th century. While most companies were primarily active in the European markets, including France, Germany, Austria, Belgium, the UK, and Finland, a number or companies had a global footprint, particularly those offering multiple types or multi-component DHTs.

To gain varied perspectives, participants were divided based on company size and technology type. Three focus groups were organized according to the type of technology developed: mHealth, Telemedicine and AI. A fourth focus group specifically targeted major industry developers affiliated with MedTech Europe, while a fifth focus group included a mixed group of developers that could not attend their designated technology-specific sessions due to scheduling issues. Additionally, five individual interviews were conducted with large industry players (see Table 5). The inclusion of both early-stage ventures, industry leaders and different type of DHTs ensured a broad view of the challenges and needs shaping DHT development, evidence generation and market access across Europe.

Table 5. Technology developers participating in the interview & focus group sessions (based on Mezei et al., 2025). In total, the study captured input from 31 unique digital health companies. Of these, 20 participated in the survey phase (following exclusion of incomplete responses), while 29 contributed to the interview and focus group phase. Some companies engaged in both phases, resulting in a combined dataset representing 31 distinct organizations developing mobile apps, telemedicine solutions, AI-based technologies or other. Some companies (n=2) engaged more than one representative in the interview phase. This was accounted for when calculating the number of unique companies represented.

Type of interview	Survey	Type of technology	Country of main market	Established
Focus Group: Mobile App	Yes	mHealth	Italy	2021
Focus Group: Mobile App	Yes	mHealth	Germany	2018
Focus Group: Mobile App	Yes	mHealth	France, Belgium, UK	2020
Focus Group: Mobile App	No	mHealth	Germany	2019
Focus Group: Mobile App	No	mHealth, Telemed	Germany	2017
Focus Group: Mobile App	No	mHealth	France	2017
Focus Group: Telemed	Yes	Telemed, mHealth	Austria	2015
Focus Group: Telemed	Yes	Telemed, AI	Ukraine, Germany	2019
Focus Group: AI	Yes	AI	US	2002
Focus Group: AI	Yes	AI, mHealth	Poland	2021
Focus Group: AI	No	AI	France	2020
Focus Group: Mixed	No	mHealth, Telemed	Finland	2020
Focus Group: Mixed	No	Robotics	Finland	2008
Focus Group: Mixed	No	mHealth	Finland	2020
Focus Group: Mixed	Yes	mHealth, Telemed	France, Germany, UK	2000
Focus Group: Mixed	Yes	mHealth, AI	Austria	2019
Focus Group: Mixed	No	AI	Austria	2018
Focus Group: Mixed	Yes	mHealth	France	2016
Interview	Yes	mHealth, Telemed, AI	Global	1896
Interview	Yes	Telemed	Germany	2000
Interview	Yes	mHealth, Telemed, AI	Global	1888
Interview	Yes	mHealth, Telemed, AI	Global	1888
Interview	No	mHealth, Telemed, AI	UK	NA
Focus Group: MedTech Europe	No	mHealth, Telemed, AI	Global	1989
Focus Group: MedTech Europe	Yes	mHealth, Telemed, AI	Global	1949
Focus Group: MedTech Europe	Yes	mHealth, Telemed, AI	Global	1896
Focus Group: MedTech Europe	No	mHealth, Telemed, AI	Global	1891
Focus Group: MedTech Europe	No	mHealth, Telemed, AI	Belgium	NA
Focus Group: MedTech Europe	No	mHealth, Telemed, AI	Belgium	NA
Did not attend	Yes	mHealth	France	2019
Did not attend	Yes	AI	Spain	2021
Did not attend	Yes	mHealth	Poland, Germany	2017
Did not attend	Yes	Telemed	France	2016

During the process of thematic analysis and coding, it became apparent that the insights shared by participants are more coherently and meaningfully interpreted when situated along the development and adoption lifecycle of digital health technologies. Therefore, the subchapters

describing results are organised in a DHT lifecycle oriented structure, reflecting key milestones in the pathway to market access, HTA evaluation, reimbursement, and broader system-level implementation (see Figure 4).

4.2.2.2 Regulatory aspects

Regulatory compliance consistently emerged as one of the earliest and most resource-intensive barriers faced by DHT developers. While developers recognised the importance of regulation in ensuring safety, performance and trust, many expressed concerns that existing pathways are ill-suited to the iterative and software-driven nature of digital innovation.

The process of obtaining MDR-compliant CE certification was described as a substantial in terms of both **financial and organisational investment**. Developers, particularly SMEs, emphasised that the costs associated with quality assurance, clinical validation, cybersecurity and documentation often outweigh the initial development costs of the DHT itself. For startups, these early compliance obligations were not only resource-intensive but also had direct implications for investor timelines. As one SME noted: "*Before we could even show anything to a hospital, we had already spent most of our seed funding on regulatory and certification procedure alone"*. Larger developers acknowledged these burdens but were generally better equipped to absorb the workload and investment through their regulatory teams and diversified revenue streams.

While the MDR provides a harmonised basis for certification, local **variations in how EU-level regulation are interpreted and applied** hinder scalability. While obtaining CE certification under the MDR was generally regarded as a foundational requirement for market entry, developers emphasized that CE-marking is far from sufficient to ensure access across the EU Member States. Rather, it initiates a second wave of national-level or local compliance demands, which vary considerably across countries and institutions. One participant from a telemedicine startup explained: "*We got CE marked and thought we were good to go in Europe. But then came five new requests from five countries, one wanted HL7 integration proof, another wanted a national security audit, and another expected an ethics board approval just to pilot."* This points to a deeper misalignment between MDR regulation and national enforcement practices.

Several SMEs described the concerns about the **cumulative regulatory burden** when requirements from different frameworks overlap. For example, combining MDR, GDPR, the EHDS and countries imposing their own certification, documentation and procedural

requirements. This was often described as creating duplication of effort, especially in relation to cybersecurity, interoperability and data protection. A mobile app developer commented, *"Even if we comply with the same regulation, every local authority asks for something different. The workload multiplies instead of being streamlined."* For instance, in Germany, developers noted the need to comply with DiGA-specific quality, interoperability, and data protection criteria set by the BfArM, including mandatory integration with national electronic health records and provision of structured machine-readable data. This was often perceived as particularly difficult for SMEs without dedicated regulatory teams.

Overall, while regulation in itself was not seen as a barrier by developers, the current design and application of regulatory frameworks were reported to impose burdens, especially in case of SMEs. While national prerequisites (beyond the scope of MDR requirements) can support safer integration, data quality, and scale, they may create variability and added costs for developers, particularly SMEs, when expectations differ across countries. This complexity, variability, and costs associated with compliance may delay or even stop market entry. Developers called for greater clarity, harmonisation, and proportionality in regulatory processes, with one respondent summarising: "*We're not asking for less regulation, we need smarter regulation that fits the day-to-day reality of digital health."* These insights highlight that addressing regulatory misalignment is a foundational step in making DHT-specific HTA frameworks both usable and effective across Europe.

4.2.2.1 Evidence requirements

Developers across company types consistently described evidence generation as one of the most significant challenges in bringing DHTs to market. While they recognised the necessity of rigorous evaluation to ensure safety and credibility, they also pointed to a persistent misalignment between traditional evidence standards and the characteristics of digital innovation. As one SME developer explained, *"We are asked to prove things the same way as pharma, but our product evolves every few months, by the time the RCT finishes, we already had ten software updates."* This illustrates the tension between agile development cycles and static evidence requirements, which many developers saw as both disproportionate and unsustainable.

A widely shared concern related to the **feasibility of RCTs** for DHTs. Many interviewees argued that RCTs are costly, time-consuming, and often ill-suited for software-driven technologies that evolve rapidly. A startup emphasised this imbalance: *"The development costs are maybe a tenth of what it takes to run a trial. The business risk isn't in the product, it's in the evidence*

expectations." While recognising that RCTs may remain appropriate for certain high-risk technologies such as AI-based diagnostic tools, developers advocated for more proportionate and flexible methods. These included RWD collection, simulation environments, and platform studies, which were seen as better aligned with iterative development and user-dependent effectiveness. Early access pathways coupled with temporary reimbursement such as Germany's provisional DiGA listing or France's PECAN scheme were broadly viewed as promising responses to these needs. These allow developers to generate RWE while the technology is already integrated into care settings.

In addition, developers highlighted that **infrastructure limitations remain a critical barrier to the use of new evidence methods**. The absence of structured data collection systems, fragmented national standards, and the lack of recognition of RWD within formal assessments significantly restrict the implementation of real-world methodologies. Without interoperable datasets and consistent validation practices, developers cannot reliably generate or submit evidence that would be accepted across multiple jurisdictions. Participants noted that this leads to duplication of effort and lost opportunities to capture the full value of digital solutions in practice. A promising development in this regard is the European Health Data Space (EHDS), which aims to harmonise standards for health data access and use across Member States. If implemented effectively, the EHDS could provide the infrastructure necessary to support RWD collection, enabling more proportionate and timely evaluations of DHTs.

This **misalignment in the domain-level evidence expectations** was another recurring theme. While developers acknowledged that core HTA domains such as clinical effectiveness and safety remain essential**,** they felt that current frameworks fail to account for digital-specific factors when assessing added value. Organisational and process-related outcomes, usability, interoperability, patient adherence, and data security were frequently mentioned as integral to the value proposition of DHTs. As one telemedicine company stressed, their innovativeness was care pathway redesign, but *"no one is really assessing health system-level outcomes, only clinical endpoints."* Similarly, an AI developer noted, *"explainability of algorithms and the representativeness of the training dataset are critical, yet these are rarely reviewed systematically by HTA agencies."* These perspectives echo survey results presented earlier, where developers consistently ranked factors such as patient readiness, adherence and privacy/security in their development planning among the highest priorities.

The findings reveal that current evidence requirements remain poorly aligned with the realities of digital innovation, creating barriers that disproportionately affect SMEs. Traditional reliance on RCTs and static endpoints limits timely evaluation and overlooks digital-specific dimensions such as usability, interoperability, and algorithmic transparency. Developers therefore called for greater recognition of alternative evidence models that incorporate RWD and support iterative re-assessment, alongside clearer guidance on digital-specific criteria.

4.2.2.2 Market access

Securing market access represents a decisive step for DHT developers, yet it was perceived as the most unpredictable and resource-intensive part of the innovation journey. Unlike pharmaceuticals or medical devices, where established procedures offer a degree of predictability, DHTs face a patchwork of evolving frameworks across Europe. This fragmentation creates substantial uncertainty, particularly for smaller companies with limited resources. Developers consistently highlighted that **fragmented market access environments** impose considerable costs. SMEs reported that they routinely hire external consultants in each country of interest to navigate the regulatory and reimbursement landscape. As one SME put it, "*We just don't have an overview of the different national requirements. […] We almost always end up hiring local experts to tell us how to enter a specific market.* Developers consistently highlighted that fragmented and rapidly changing market access environments cause uncertainty. This lack of convergence not only delays market entry but also inflates costs, disproportionately affecting smaller firms. While large industry companies utilise in-house market access expertise, SMEs rely on consulting external experts and often managing contradictory advice.

A further concern is the **instability of requirements within existing frameworks**. Developers shared that evidence once deemed sufficient could later be rejected due to regulatory updates mid-process. One AI startup recounted: *"It's like a moving target, you think you know what evidence you need to provide, you make the investment decision to start the process and then comes another change in the requirements and regulations."* Such shifts not only erode trust in the process but also represent sunk costs that SMEs are rarely equipped to absorb. Recent policy updates, such as revisions of Belgium's mHealth pyramid (2021 to 2023) or the German DiGA scheme under the DigiG in 2024, illustrate this dynamic. While such reforms aim to strengthen frameworks, developers emphasised that frequent changes create instability and discourage investment in development of DHTs.

Participants described predictable and proportionate frameworks as equally critical to market success as methodological rigour, since they shape strategic choices about which countries to enter. They have repeatedly reported prioritising market entry into countries with robust digital infrastructures and clearer rules, as these markets offer quicker uptake and fewer integration challenges. They are also prioritising entry into those select markets where a clear and predictable link exists between evaluation and national level public funding, as these directly translate into reimbursement or system-wide uptake more often than in other countries. This tendency may deepen inequities across Europe, as digitally mature countries attract innovation while less mature systems are left behind. Without greater convergence and stability, Europe risks reinforcing uneven access to digital health innovation.

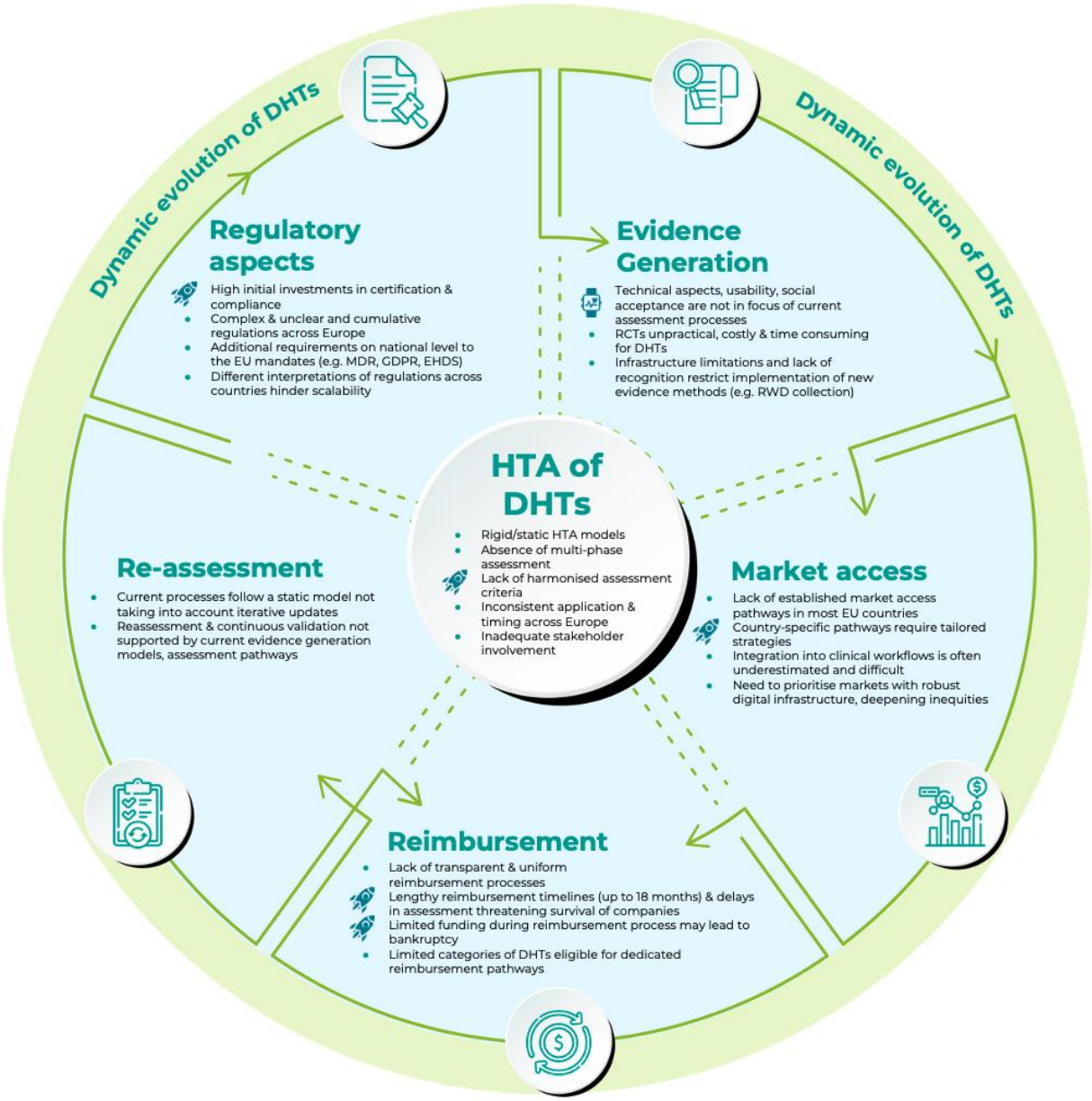


Figure 4. Key challenges and barriers of developers visualized along the lifecycle of DHTs

(Source: based on Mezei et al., 2025). Journey of the DHT along the lifecycle is visualised by the green arrows, starting from Regulatory aspects to Re-assessment (informing reimbursement). The figure does not aim to represent all lifecycle phases of DHT development and implementation but rather offer a high-level overview of the main stages where developers typically face challenges and barriers. The central placement of HTA reflects its role not as a single lifecycle stage, but as a dynamic instrument that could support DHT development and implementation throughout their lifecycle. Challenges disproportionately impacting SMEs are marked with a startup rocket icon. Challenges that where differences between type of technology (mHealth, telemedicine, AI) were observed are marked with a smartwatch icon.

4.2.2.3 Health Technology Assessment

HTA emerged repeatedly in the interviews as both a cornerstone and a bottleneck for digital health adoption. Developers recognised that HTA is indispensable for ensuring safe, effective and equitable adoption of digital health, but underscored that in its current form imposes disproportionate burdens on developers and fails to reflect the realities of digital innovation. They therefore did not call for lowering assessment standards, but for proportionate, predictable and transparent frameworks.

In terms of key challenges, participants highlighted that **static HTA processes** fail to reflect the dynamic nature of DHTs Frequent software updates, agile development cycles, and user-driven evolution clash with lengthy HTA timelines. Developers pointed out that by the time a HTA review is complete, the assessed version of a DHT may already be outdated. "*The process assumes health technologies are fixed, but ours change every few months*" an SME developer explained. This disconnect was perceived as leading to assessments that are quickly obsolete, undermining both validity and usability for decision-makers, while creating unnecessary workload for developers.

Another key theme was the **absence of proportionate, multi-phase assessment models** that scale with the maturity of the technology. Developers argued that early-stage solutions are often held to the same evidentiary standards as mature, widely deployed interventions, which can be prohibitive for small companies. One startup explained, "*If you need to deliver the same level of evidence before you even reach the market, you never get the chance to grow, not to mention survive."* Many pointed to tiered approaches, such as those inspired by Technology Readiness Levels (TRLs) as potential solutions. Under such models, preliminary or conditional assessments could be applied to early-stage DHTs with limited but targeted evidence requirements, while more advanced solutions would face progressively higher evidence requirements. This was seen

as a potential way to allow earlier market entry and real-world utilisation without compromising safety, clinical performance, or transparency.

A central challenge noted was the **lack of harmonisation across countries**. Developers reported having to tailor HTA dossiers to varying national requirements, often re-submitting the same evidence in different formats or being asked to generate additional data to meet different standards. This lack of alignment was described as both inefficient and discouraging, with one SME noting: "*It feels like we are redoing the same work five times over. Every country asks for something slightly different."* Beyond inefficiencies, this fragmentation was also seen as a barrier to scalability, with firms forced to prioritise larger or more digitally mature markets rather than rolling out across Europe simultaneously. In addition to divergent requirements, developers underlined the inconsistent application and timing of HTA across Europe. In some countries, HTA is systematically embedded into market access and reimbursement decisions, while in others it is applied selectively or with significant delays. Such inconsistency makes it difficult for developers to plan evidence generation strategies and adds to the perceived risk of investing in European markets.

Finally, participants pointed to **limited stakeholder involvement in HTA** design and assessment processes. Opportunities for early dialogue with HTA bodies were perceived as ad hoc and inconsistent across Europe. Developers called for more structured and accessible pre-submission consultation opportunities, particularly for novel digital interventions. Such interactions were seen as essential to de-risk evidence strategies, prevent late-stage rejection, and foster greater alignment between developers and assessors. Transparency of HTA agencies on already conducted assessments were seen as valuable references for developers on study type, sample size, outcomes and other aspects. The publication of each Digi-HTA assessments conducted by FinCCHTA was noted as a good example.

The central placement of HTA in Figure 4. reflects its role not as a single lifecycle stage, but as a dynamic instrument that could support DHT development and implementation throughout their lifecycle. Developers argued that HTA should begin to play a role as early as the regulatory certification phase, for example through early-HTA o guide investment and evidence strategies, and continue during real-world use, where adaptive re-assessment is critical to capture ongoing performance, safety, and system-level impact. From this perspective, HTA is not only a decision gate but a tool for enabling proportionate, predictable, and iterative evaluation of innovation.

4.2.2.4 Reimbursement

In the transition from market entry and HTA to broader adoption, reimbursement emerged as one of the most complex challenges for developers. Participants across all developer types described reimbursement as the critical bottleneck to scaling**,** particularly in the absence of transparent, predictable and DHT-specific processes in the majority of European countries. Developers consistently stressed that without reimbursement, even clinically validated solutions cannot reach widespread adoption: *"If reimbursement doesn't follow, investors will pull out, and that's the end of the road."*

The first challenge relates to **the lack of transparent and uniform reimbursement processes**. Only a small number of countries, e.g. Germany, France and Belgium, link DHT-specific assessment frameworks with reimbursement mechanisms in Europe. They described reimbursement systems as "opaque", with limited guidance on what constitutes sufficient evidence, which domains will be prioritised, and how pricing negotiations unfold. The lack of transparency leaves developers uncertain about how to design their evidence strategies and prolongs the timeline between clinical validation and patient access. They have reported preference for those markets a link exists between evaluation and national level public funding. In Finland where the centralised assessment framework is not connected to reimbursement, requirements of the Digi-HTA were perceived more as useful guidelines or "good-to-have" when approaching local purchasers, rather than formal routes to securing funding and scaling nationally. One participant noted that in Finland, having a Digi-HTA report was appreciated during procurement discussions but did not directly translate into reimbursement or system-wide uptake.

In countries where a dedicated assessment framework for DHTs has been implemented and coupled with reimbursement, participants reported that **reimbursement eligibility was often restricted** to a narrow subset of DHTs, such as patient-facing tools or those with therapeutic functions. Several types of DHTs are not eligible to apply for reimbursement through some of the dedicated pathways, such as diagnostic tools, non-patient facing tools or solutions that improve workflow. Developers feel that markets are currently cherry picking DHTs, when the biggest added value would be in primary and secondary prevention. In the words of one telemedicine SME, *"The market is rewarding what's visible to the patient, not what fixes the*

system." This is seen as a missed opportunity by developers, especially for solutions aimed at primary or secondary prevention and DHTs with organisational and system-level value.

Where frameworks do exist, **lengthy timelines** were reported as a major concern. Several participants shared concerns over the length of reimbursement procedures, as they often take over a year, in some cases up to 18 months. One industry representative described a situation where, after conducting costly validation trials in Germany, the slow reimbursement processes and delayed pay-out jeopardised the continuation of the product. They ultimately cut the product and absorbed the financial loss from other profitable business units. *"Start-ups can't do that. They don't have other business lines to fall back on. If reimbursement doesn't follow, investors will pull out, and that's the end of the road",* reflected the participant. SMEs and startups reported a disproportionate burden when operating under these timelines, as for smaller companies reliant on external investment this delay is not just a strategic inconvenience, it can pose an existential threat. If initial efforts are unsuccessful, securing further investment can be challenging, leading to potential project termination or even bankruptcy. This unfavourable regulatory environment may also incentivise companies to shift focus toward markets with simpler, more predictable regulatory requirements such as the US or China.

Closely linked to the issue of timelines is the **lack of interim funding support during evidence generation and reimbursement procedures** are ongoing. Developers explained that the high costs of maintaining operations, combined with the delay in generating revenue from reimbursed uptake, often forced early-stage companies to rely entirely on venture capital. When timelines exceeded expectations, several participants described facing liquidity crises that threatened bankruptcy. Developers welcomed the concept of preliminary reimbursement schemes (e.g. Germany's provisional DiGA listing or France's PECAN pathway), where reimbursement is granted while further evidence is collected. This early access model was seen as more realistic and innovation-friendly, as it allows developers to test their technology in real-world settings and collect data in a more flexible manner. Several participants also noted that RWD generated under these schemes often proved more useful and contextually relevant than pre-market clinical trials, especially for iterative or adaptive digital technologies. These schemes were seen not only as a financial tool, but also as a structural signal that systems are willing to align evaluation procedures with the innovation cycle of DHTs.

As a potential strategy to mitigate the risks associated with unclear or delayed national-level reimbursement, several developers reported adopting a bottom-up approach to market entry. Rather than waiting for centralised HTA decisions or public reimbursement approval, these companies actively engage with local payers or healthcare providers to demonstrate the value of their solution directly. This tactic includes building local pilot projects, collecting real-world outcomes, or targeting specific hospital systems for direct purchase. As one mobile app SME explained, "*We went to regional hospital groups to show the clinical impact and got them to fund us through innovation budgets. Waiting 1,5 years for a national listing was not possible."* In markets where no clear reimbursement framework exists or where types of DHT are not eligible for reimbursement, this localised purchaser-driven route becomes a practical workaround. While it may not lead to long-term scalability, it offers a timely path to market, particularly for early-phase companies needing revenue to survive.

4.2.2.5 Re-assessment

Re-assessment also emerged as a concern for developers, reflecting the mismatch between the **static nature of current HTA** models and the dynamic evolution of digital health technologies. While pharmaceuticals and many medical devices often remain stable after approval, DHTs typically undergo frequent updates, modifications, and refinements driven by user feedback, regulatory demands, or technological advancements. Developers emphasised that existing HTA processes rarely accommodate these iterative cycles, creating a disconnect between regulatory approval, evidence generation, and ongoing clinical use. This highlights a broader systemic issue: HTA outputs are treated as static verdicts, whereas DHTs require adaptive and longitudinal evaluation. The lack of recognition for continuous data collection or RWE further compounds this challenge, leaving developers with limited opportunities to demonstrate improvements achieved post-launch.

Challenges linked to re-assessment are closely tied to earlier stages of the evaluation cycle, particularly evidence generation and market access. The difficulties of producing RWE, the absence of infrastructures for structured data collection, and the lack of consistent methodologies for iterative validation were repeatedly cited as barriers to meaningful re-assessment. A telemedicine firm noted, *"We can collect outcomes in real-world use, but there is no pathway to bring this evidence back into the assessment process."* Without such feedback loops, HTA risks undervaluing DHTs that improve incrementally over time and discouraging developers from investing in continuous quality enhancement.

In conclusion, re-assessment was widely seen as a necessary but underdeveloped component of DHT evaluation. Developers advocated for adaptive models that incorporate continuous validation, enable the use of RWE, and scale evidence requirements according to maturity and real-world performance. While such approaches could reduce redundancy and improve the timeliness of evaluations, they would also help ensure that HTA reflects the dynamic realities of digital innovation. Importantly, the challenges of re-assessment overlap with those identified at earlier stages, reinforcing the need for a lifecycle-sensitive approach to HTA that does not end with market entry but evolves alongside the technology itself.

4.3 Recommendations for DHT-specific HTA

4.3.1 Overview of gap analysis results

The consolidation of findings across the survey, interviews, and focus groups highlights the persistent gap between the current design of HTA processes and the characteristics of digital health innovation. Developers consistently reported challenges in navigating fragmented assessment pathways, unclear or shifting evidence requirements, and lengthy regulatory and reimbursement timelines. These barriers create uncertainty and discourage investment, particularly for SMEs, but they also illustrate the broader structural misalignment between pharmaceutical-oriented HTA models and the needs of digital technologies.

The gap analysis undertaken in this research confirms that these challenges are not isolated incidents but systemic inefficiencies that span the lifecycle of digital health technologies. Developers emphasised that usability, adaptability and iterative improvement remain undervalued in current frameworks, while essential enablers such as real-world evidence, lifecycle-sensitive re-assessment, and structured guidance are underdeveloped. At the same time, the analysis revealed that developers are acutely aware of these deficiencies and actively seek solutions that could better align HTA with digital innovation. Rather than calling for less regulation, their demand is for proportionate, transparent, and predictable frameworks that enable earlier access while maintaining safeguards for patient safety and health system sustainability.

In response to these identified gaps, this section sets out six overarching recommendations for DHT-specific HTA practices (Table 6). These recommendations represent the priority areas most frequently highlighted across the data. They do not aim to capture every possible developer need or suggestion but rather synthesise those elements considered most critical for *reducing*

uncertainty and enabling a better alignment between HTA and digital health innovation. By focusing on priority needs, the proposed recommendations offer a practical and scalable set of design features that could strengthen the usability of HTA frameworks and contribute to a more innovation-friendly environment across Europe. In doing so, they aim to reposition HTA from being a barrier to innovation towards becoming a more enabling and balanced policy instrument.

Table 6. Recommendations for DHT-specific HTA processes mapped against developer-reported challenges and barriers

Recommendation	**Challenges and barriers addressed**
1. Harmonise taxonomy, evidence requirements and provide a single access point	- Complex & unclear regulations across Europe - Different interpretations of EU-level regulations - Additional national requirements on top of EU mandates (MDR, GDPR, EHDS) - Duplicated HTA dossiers, wasted resources, delayed access (esp. SMEs) - Inconsistent HTA criteria & application & timing across Europe - Lack of transparent & uniform reimbursement processes
2. Multi-phase assessment tied to lifecycle of DHTs	- RCTs impractical, costly & time-consuming - Rigid HTA models not adapted to iterative DHTs - Current re-assessment processes follow a static model - Lengthy reimbursement timelines - Limited preliminary reimbursement opportunities
3. Highlight digital-specific value in assessments	- Technical aspects, usability, and social acceptance not part of current assessment - Organisational and patient-reported outcomes often excluded - Limited categories of DHTs eligible for reimbursement (system-level or preventive tools excluded)
4. Recognise and incorporate RWE	- RCTs impractical, costly & time-consuming - No recognition of RWE in assessments - Lack of support for re-assessment & continuous validation
5. Early stakeholder involvement in HTA	- Inadequate stakeholder involvement in assessment design - Resource-intensive navigation without early advice - Uncertainty and late-stage rejection due to unclear evidence expectations
6. Access to supporting material for developers	- Country-specific, rapidly changing requirements - Lack of structured, centralised guidance (“one-stop-shop”) - Trial-and-error approach leads to wasted resources - Developers hiring national experts to prepare dossiers - Risk of duplication of effort and wasted resources

4.3.2 Recommendations

1. Harmonisation of taxonomy, evidence requirements across countries and provide a single access point for DHT-specific guidance for developers:

A strong call for harmonisation emerged across the research, with developers consistently expressing *the need for a more unified and predictable approach to DHT assessment across*

Europe. While participants acknowledged that certain elements, such as country-specific budget impact or pricing negotiations, must remain under national jurisdiction, there was consensus that terminologies, core evidence requirements and assessment logics should be consistent and interpreted in a comparable manner across Member States. Currently, even in countries that have implemented DHT-specific HTA frameworks, developers reported significant variation in terminology, expectations and pathways, resulting in duplicated efforts, delayed access and inefficient resource use. This fragmentation is particularly burdensome for SMEs and startups, who often lack the legal and regulatory capacity to navigate country-specific processes independently.

Participants endorsed the idea of centralised, accessible guidelines in form of a "one-stop-shop" for DHT developers, which would provide clear, harmonised guidance on assessment requirements and processes across countries in the European region. The EDiHTA framework was frequently positioned as a candidate for this role in interviews, drawing comparisons to the FDA's Digital Health Policy Navigator (FDA, 2022), which consolidates relevant regulatory and evidence expectations into a coherent, user-friendly format. Several focus group members highlighted that having transparent, centralised guidance would significantly reduce uncertainty and help avoid costly missteps during the planning and early development phases. Participants also cautioned that harmonisation must go beyond surface-level alignment. It must ensure that *countries not only reference the same HTA domains but also interpret and apply them similarly*. Developers stressed that without harmonised implementation and interpretation, formal alignment of frameworks risks remaining purely methodological. The most frequently mentioned benefits of a harmonised access point were early-stage clarity on what constitutes sufficient evidence for different types of DHTs, efficiency in dossier preparation, reducing the need for reformatting or re-submission, increased transparency and trust in how technologies are assessed across jurisdictions and support for multi-country scaling.

In summary, developers viewed harmonisation as a critical enabler of both innovation and equity. While acknowledging the legitimate differences in national health systems, they argued that a shared foundation of assessments pathways and evidence expectations, supported by a centralised guidance platform would represent a meaningful step toward reducing fragmentation, especially for smaller players navigating complex market access routes for the first time. For uptake and sustainability of such an initiative the harmonised framework needs to be validated through pilot programs involving key European countries.

2. Multi-phase assessment tied to lifecycle of DHTs:

Developers emphasized the need for more *flexible, proportionate assessment approaches that align with the development cycle of digital health technologies*. Many called for a shift away from traditional "one-time" assessments, typically used in pharmaceutical HTA, toward a multi-phase model that accommodates earlier evaluation, iterative development, continuous improvement and re-evaluation. This was viewed as especially important for adaptive, software-based solutions that evolve post-launch. Participants have implied it would be useful if evidence requirements scaled based on the maturity of the technology, as reflected in frameworks such as the Technology Readiness Level (TRL) (NASA, 2023) or the Healthcare Innovation Cycle (CIMIT, 2018). Early-stage technologies could undergo preliminary or conditional assessments with limited but targeted evidence, while more mature or widely deployed solutions would require additional validation. This tiered approach was seen as a way to enable earlier market entry without compromising safety, clinical performance or transparency.

The EUnetHTA Core Model offers a precedent for this in its distinction between Rapid Relative Effectiveness Assessments (REAs) and Full Assessments (Kleijnen *et al.*, 2014). A rapid or early HTA could focus on core dimensions such as intended use, functionality, safety, and preliminary clinical effectiveness, while deferring comprehensive economic, organisational, or ethical assessments to later stages once the product has sufficient usage data. This would align HTA processes with both innovation timelines and evidence availability. Several participants cited the provisional listing mechanism in Germany's DiGA pathway as a valuable model. Under DiGA, products can be temporarily reimbursed while additional evidence is generated. This allows developers to enter the market, collect RWD, and refine their solution, before undergoing full re-assessment. Developers who had accessed this route noted it enabled earlier feedback loops and market validation, particularly important for SMEs needing revenue to survive.

Additionally, participants stressed that such a model must account for differences between types of digital technologies. For example, AI-based tools may require rigorous algorithm performance validation and external testing early on, while mHealth apps aimed at behavioural change may benefit from longitudinal RWD to capture real-world effectiveness. A harmonised yet flexible framework, capable of differentiating by technology type and development phase, was considered essential.

In summary, multi-phase assessment grounded in TRL or lifecycle stage was widely seen as an enabler of more timely, proportionate and innovation-sensitive HTA. Developers emphasised that such an approach, combined with conditional reimbursement and adaptive re-assessment, would better reflect the real-world pathway of digital innovation and improve the relevance of HTA outcomes for all stakeholders.

3. Highlighting digital-specific value in assessments:

A recurring theme across all developer consultations was the *limitation of traditional HTA frameworks in capturing the unique value dimensions of DHTs.* Participants mentioned that conventional assessments inherited from pharmaceutical and medical device evaluation fail to account for technical features, iterative development and context-dependent impacts characteristic of DHTs. This mismatch was seen as a key reason why some technologies struggle to achieve recognition or reimbursement despite delivering benefits to the patient or the health system.

Developers consistently called for greater emphasis on DHT-specific technical aspects such as usability, interoperability, cybersecurity, algorithmic performance and integration into clinical workflows. These factors were perceived as crucial for *measuring the real-world impact of digital solutions* but are often sidelined in traditional HTA processes. This feedback aligns with recent efforts in the HTx and EDiHTA projects to foreground technical validation as a core dimension of assessment for digital innovations.

In addition to technical criteria, developers emphasised the need for HTA frameworks to formally recognise *outcomes beyond clinical endpoints*, particularly organisational outcomes (e.g. workflow optimisation, time savings for clinicians, reduced hospital readmissions) and patient-relevant outcomes (e.g. PREMs and PROMs such as adherence, self-efficacy, satisfaction). Telemedicine developers stressed that digital interventions often deliver incremental improvements in care processes rather than dramatic changes in mortality or morbidity, outcomes that are more aligned with the nature of software-based tools. To align HTA practices with the characteristics of DHTs, future frameworks must evolve beyond a clinical effectiveness focus and shift to a more multi-dimensional, context-aware approach taking in account organisational, social and individual level impact. Developers warned that without this shift, valuable innovations risk exclusion from reimbursement systems, not because they lack impact, but because they are assessed with inappropriate tools.

In this context, several participants referred positively to the DiGA framework adding organisational and patient relevant outcomes, including outcomes like increased adherence, patient autonomy, health literacy, as a potential outcome to prove medical benefit of a DHT. Finland's Digi-HTA framework, which incorporates domains such as usability, data security, and interoperability alongside clinical effectiveness. Participants underlined that these outcome domains and technical criteria are not universally applicable but rather depend on the modality and purpose of the DHT in question. For example, transparency of training datasets and explainability were viewed as particularly important for AI-based tools, while usability and patient relevance (e.g. patient-reported outcomes) were more relevant for patient-facing applications. Developers agreed that any HTA framework must allow flexible tailoring of evidence expectations, with clear guidance on which domains apply to which types of technologies. This reinforces the importance of a modular or tiered framework structure, as discussed in previous recommendations to avoid misaligned or overly burdensome evaluations.

4. Recognising and incorporating RWE in assessments:

A widely shared view across interviews and focus groups was that traditional evidence generation models, including RCTs do not align with the development timelines or innovation cycles of many DHTs. Developers described RCTs as excessively rigid, time-consuming and cost-intensive for technologies that are continuously updated and iteratively deployed. Several participants proposed that RWE could serve both as a complement to pre-market evidence and as a mechanism for adaptive re-assessment over time. This was seen as especially important in early phases of market access, where evidence from RCTs may not be feasible to generate. France's PECAN programme was mentioned as a relevant model, allowing DHTs to be reimbursed for up to 12 months, while additional data is being collected to apply for permanent reimbursement. Germany's DiGA pathway was also brough up as a positive example, where developers may gain provisional reimbursement status while collecting RWE to substantiate claims of medical benefit. These early access schemes were not only viewed as enabling tools for evidence generation but also as system-level signals that public payers are open to innovation-adaptive forms of evaluation.

Beyond feasibility, many developers highlighted the contextual validity of RWE, arguing that such evidence better reflects the everyday realities of implementation and user engagement, dimensions that are difficult to assess in controlled trials. This was particularly emphasized for

technologies addressing behavioural change, chronic disease management or patient self-monitoring, where usage patterns and adherence often determine effectiveness. For such interventions, developers proposed that routinely collected data, e.g. on patient engagement, drop-off rates or clinical workflows should be considered essential indicators of real-world performance.

However, developers also cautioned that the integration of RWE into HTA frameworks must be accompanied by clear methodological guidance. Concerns were raised about the current ambiguity regarding which types of RWD are acceptable, how to ensure data quality and how such evidence will be judged in comparison to traditional trial-based results. While Germany's DiGA pathway allows for alternative evidence generation models, such as meta-analyses, experimental intervention studies and some observation studies (BfArM, 2019), only one DiGA has been accepted so far based on evidence provided from alternative (non-RCT) models (BfArM, 2025). Causal inference is more difficult than in RCTs and managing challenges such as patient selection, data representativeness, and data privacy/security will be key issues for the practical success of implementing RWE in the German context (Brönneke et al., 2023). Without clarity on what is expected in form of RWE, developers feared that attempts to incorporate RWE could be lagging behind and instead of accelerated. This has been echoed by recent research prioritizing topics for the use of RWE in DHT assessment, including missing data, study endpoints, comparator groups, multimodal interventions, study questions, equity, generalizability, confounders and fit-for-purpose approaches (Stern *et al.*, 2022; Srivastava *et al.*, 2023).

To address these concerns, it is recommended that a *HTA framework for DHTs should explicitly define the role of RWE within a multi-modal evaluation model and offer guidance on suitable data sources, analytical methods and quality standards.* This would not only enhance the legitimacy of RWE in assessments but also reduce uncertainty for developers planning their evidence generation strategies. The approach would enable DHTs to enter the system earlier and demonstrate value dynamically, rather than being excluded due to an inability to meet conventional pre-market expectations. This view aligns with recent EU initiatives such as the Horizon 2020 HTx project and European Medicines Agency's (EMA) DARWIN EU initiative, which explicitly aimed to integrate RWE into decision-making and promote personalised, dynamic HTA processes (HTx Project, 2020; EMA, 2025). Similarly, the EUnetHTA Core Model as well as ongoing work by the EvaluDMD Taskforce acknowledged the importance of leveraging RWE to inform assessments (EUnetHTA, 2022; Boers *et al.*, 2025).

Participants flagged that the limitations of current infrastructure across many European countries, lack of interoperable data systems and incomplete digitisation in certain health systems might limit the uptake of RWE utilisation. Several developers expressed concern that the lack of interoperable data systems and incomplete digitisation in certain health systems may restrict the feasibility of robust RWE generation. In particular, developers with experience in Southern and Eastern Europe noted that digital data availability, standardisation and access protocols remain insufficient to support RWE generation envisioned in more advanced frameworks. As a result, countries without adequate infrastructure risk being excluded from emerging evidence-based innovation pathways, further increasing inequalities in DHT adoption and reimbursement. Without the structural enablers, the potential of RWE to support timely, flexible, and innovation-sensitive evaluation processes cannot be fully realised.

5. Early stakeholder involvement in HTA:

Several participants expressed a need for improved access to HTA-specific methodological guidance during the early stages of development. Developers consistently reported uncertainty around how to generate the type and quality of evidence that would be expected in a formal assessment context, especially given the diversity of requirements across countries and product types. To address this gap, participants strongly supported the idea of *integrating structured consultation opportunities into the HTA process*. Such mechanisms could take the form of scheduled advisory sessions, either with HTA agencies themselves or with a pool of certified, independent experts. These sessions would allow developers to receive early feedback on their evidence strategies and better align their development activities with expectations for market access and reimbursement. Participants noted that receiving timely advice at multiple points throughout the DHT lifecycle (e.g., before clinical validation or prior to dossier submission) could prevent costly misalignments and support more targeted, efficient data generation.

One of the most frequently cited positive examples was Germany's DiGA fast-track pathway, which offers optional scientific advice (Wissenschaftliche Beratung) to developers during the early phases of evidence planning. Several participants who had accessed these consultations described them as helpful, noting that the process enabled them to align their study design with BfArM expectations. Similarly, France's PECAN pathway also allows for pre-submission meetings with HAS, enabling dialogue around methodological design and anticipated evidence gaps. While fewer participants had direct experience with the French system, those who did emphasized that such interactions, helped reduce the risk of misalignment and contributed to a more targeted and efficient submission process.

Beyond one-time consultations, developers advocated for an ongoing dialogue model in which assessment bodies, developers, and other stakeholders, such as healthcare professionals or patient representatives, engage regularly to ensure that methodological decisions remain proportionate and context sensitive. This type of iterative engagement was seen as especially important for SMEs, which often lack in-house regulatory expertise and cannot afford extended timelines or multiple failed submission attempts. To operationalise this, some participants proposed establishing a centralised pool of experts, coordinated through the EDiHTA initiative or national HTA agencies, from which developers could commission independent, structured advice. This would provide a credible and accessible resource for smaller developers while avoiding the bottlenecks often associated with direct HTA body consultations. Ultimately, developers agreed that creating a *structured, multi-stakeholder consultation mechanism would reduce procedural uncertainty, improve the quality of submissions and help accelerate time to market and reimbursement.*

6. Access to supporting material for developers:

In terms of format of supporting material for developers, while checklists are helpful for keeping processes on track, they could oversimplify complex regulatory steps and miss nuances important for comprehensive compliance. A guideline and an interactive platform would be a useful format of the future EDiHTA framework from industry perspective. This could offer structured guidance through the evidence generation and compliance processes, enabling a clear step-by-step approach, efficiently navigating complex requirements, minimizing the trial-and-error approach. This was envisioned as a resource that would be updated in real-time to reflect changing regulations and provide targeted advice. Participants pointed out that such a platform would allow for a personalized experience, guiding them through compliance specifics relevant to their DHTs. Industry representatives have cautioned that there might be hesitancy to input data about their innovations due to concerns over revealing proprietary information. This hesitation could limit the platform's usage and effectiveness if developers feel it compromises their competitive edge. Webinars/videos/training material for different stakeholders explaining different topics in the field was highlighted as an efficient way of navigating the regulatory and assessment environment.

Detailed documents of already conducted assessments utilised as best practices and case studies, were seen as valuable supplements to other tools. Apart from useful *references for developers on study type, sample size, outcomes and other aspects, a case study repository of already conducted*

assessment were seen as ways to foster transparency on processes. Apart from fostering transparency, these can offer deeper insights into navigating the HTA landscape and highlight successful strategies used by similar technologies.

4.4 Summary of scientific contributions

1) DHT-specific HTA practices remain limited and fragmented across Europe, with significant variation in scope, methodology and reimbursement mechanisms in place across countries (H1) **(**Mezei et al., 2023, Boers et al., 2025). The literature review identified nine HTA frameworks adapted for DHTs across Europe. Germany, France and Belgium have developed fast-track HTA and reimbursement pathways, others, like Spain and Finland and United Kingdom remain in earlier stages of institutionalisation, while the majority of Member States do not have DHT-specific HTA practices in place. *The comparative review of the nine HTA frameworks revealed substantial variation across in how DHTs are defined, assessed, and linked to reimbursement.* Differences in the HTA frameworks span from terminology to the number and type of evaluation domains as well as the linkage to reimbursement pathways. The limited number of HTA frameworks and the differences in these frameworks, complicate the planning and scaling of DHTs in the region, delaying market access and discouraging developers from pursuing multi-country market access strategies in the European region.

2) Developers see HTA in its current form as a barrier for market access and scaling of DHTs due to its misalignment with characteristics of digital innovation. (H2 a) (Mezei et al., 2025). The research identifies critical structural barriers that developers encounter across the lifecycle of DHTs. *Regulatory complexity, high evidence requirements, fragmentation and inadequate guidance create barriers at early stages, while rigid, static HTA models often fail to accommodate digital specific aspects like iterative updates or assessment of technical, patient-facing or social impact.* Reimbursement procedures tend to be unclear or poorly adapted to digital technologies, and re-assessment models rarely account for ongoing improvements of technologies. Together, these findings point to a mismatch between HTA system design and the agile, iterative nature of digital health development, reinforcing the need for a more dynamic and agile assessment model.

3) Developers face a shared set of challenges, but SMEs lack the capacity to respond to them compared to large companies, threatening the existence of SMEs on the European digital health market (H2 b). Developers across the study identified a set of shared challenges

that hindered market entry and scaling, with data indicating minor differences in the nature of the challenges different type of DHT developers face. These differences were visible per type of technology with AI developers facing challenges linked to algorithm validation, transparency, and data access, telemedicine developers highlighted barriers around interoperability and integration into established care pathways and mHealth developers focusing on challenges with demonstrating value apart from clinical outcomes. While developers appeared to face shared set of barriers, their ability to manage them were different. SMEs described difficulties in meeting varying and unclear evidence requirements while maintaining commercial viability threatens their survival before being able to scale. By contrast, larger companies reported to absorb costs and withstand lengthy HTA procedures better than SMEs through dedicated regulatory teams and larger financial reserves. This difference may indicate that *the current European policy and HTA environment, while a barrier to digital health innovation in general, can threaten their survival of SME innovators in the digital health market.*

4) Adapting the HTA process by closing the gap between challenges of developers and characteristics of digital innovation will shift HTA from being perceived as a barrier to a driver of innovation (H3). HTA frameworks must adopt harmonised, flexible and lifecycle-sensitive approaches, including earlier stakeholder engagement, structured use of RWD and differentiated pathways based on technology type to **respond to the needs of DHT developers (**Mezei et al., 2025). Drawing on policy mix analysis indicates that adapting HTA frameworks to the characteristics of digital innovation should be viewed not in isolation, but as part of the broader policy mix shaping digital health in Europe. Developers described how barriers to market access emerged at the intersection of regulatory requirements, reimbursement frameworks, and evidence expectations, suggesting that HTA functions as one element within a wider set of instruments that either constrain or enable innovation. The research proposes six concrete recommendations that support the development of an adaptive HTA frameworks for DHTs. These include: *1) harmonising taxonomy, evidence requirements across Member States and streamlining information and assessment processes, 2) structuring multi-phase assessments around DHT lifecycle phases, 3) recognising DHT-specific value dimensions beyond clinical endpoints, 4) integrating RWE into evaluation, 5) enhancing stakeholder interaction through the HTA process, and 6) offering access to supporting materials and structured guidance for developers.* These proposals aim to increase the responsiveness, transparency, and usability of HTA frameworks, particularly for smaller developers navigating complex systems.

Implementing adaptations within HTA, such as proportionate evidence requirements, more flexible assessment timelines, and clearer pathways for re-assessment, could therefore reduce the bottlenecks currently experienced by developers. When embedded within a supportive policy mix that also includes regulation, data infrastructure, and financing mechanisms, these changes may act as an enabler of digital health innovation across the region, allowing technologies to scale more sustainably and equitably.

5) DHT-specific HTA processes need to strike a balance between over-regulation and under-regulation to position it as part of a deliberate policy mix that actively incentivises innovation while maintaining accountability and evidence-based decision-making. A key contribution of this study is the demonstration that innovation cannot and should not be enabled at the expense of patient safety or health system resilience. The findings highlight the importance of striking a balance: avoiding over-regulation, which risks blocking SMEs and startups with unrealistic evidence demands, while also avoiding under-regulation, which could result in unsafe or ineffective technologies entering care. In this sense, HTA reform is not about lowering the bar, but about making the process fit-for-purpose for digital health. This requires a shift from viewing HTA purely as a gatekeeping tool towards positioning it as part of *a deliberate policy mix that actively incentivises innovation while maintaining accountability and evidence-based decision-making.*

5 Discussion

5.1 Main findings

5.1.1 Hypothesis 1 (H1)

The first hypothesis stated that *DHT-specific HTA practices remain limited and fragmented across Europe, with significant variation in scope (technologies included), methodology (domains assessed), and reimbursement mechanisms.* This hypothesis is important because the institutionalisation of DHT-specific HTA is central to whether Europe can provide predictable and transparent access pathways for digital health technologies. Understanding the current state of institutionalisation is therefore essential to assess its implications for developers and policymakers.

Findings from the systematic literature review provide strong support for Hypothesis 1. Nine DHT-specific HTA frameworks were identified across 7 European countries, namely in Germany, France, Belgium, Spain, Finland, the United Kingdom and Scottland. The frameworks

demonstrate significant differences in the scope of technologies they cover, the methodological criteria applied, and the linkage to national level reimbursement (see Table 3). While the institutionalisation of DHT-specific HTA is clearly in progress in the European region, it remains shaped by national priorities, regulatory readiness and institutional capacities. The reviewed frameworks show that European countries are at different stages of developing proportionate, transparent and innovation-sensitive HTA models and that convergence remains limited. While national-level progress is undeniable, this study confirms that the European HTA landscape for DHTs is not underpinned by a consistent methodological approach.

Analysis of the frameworks demonstrate significant differences in the scope of technologies they cover, the methodological criteria applied, and the linkage to national level reimbursement (see Table 3). The frameworks apply different taxonomies and classification systems to define and group DHTs with some focusing on mobile health apps (e.g. mHealth in Belgium), others include broader categories such as AI-based technologies (e.g. Spain's AQuAS, Finland's Digi-HTA), and some distinguish DHTs based on risk or use context (e.g. UK's ESF). Further differentiation was observed in two countries implementing multiple schemes (e.g. Germany's DiGA and DiPA, France's LATM and PECAN).

This finding is consistent with previous literature, including Coder et al. (2024), Mezei et al. (2023) and Boers et al. (2025) which highlight the lack of a shared European understanding of what constitutes a DHT in HTA context and which DHTs are eligible for assessment. The inconsistency in taxonomy and categorisation not only reflects national differences in classification systems but also shapes both the scope of evaluation and the criteria used to assess them in each country. While countries like Finland and Scotland have adopted broader evaluative logics that integrate usability, cybersecurity, and interoperability, others maintain more traditional models focused on clinical outcomes and cost-effectiveness. As shown in Boers et al. (2025), even frameworks that reference similar criteria often differ in how those criteria are applied, interpreted, or weighted. The link between HTA and public reimbursement further reinforces this fragmentation. Only 3 of the 7 countries reviewed (Germany, France, and Belgium) offer institutionalised reimbursement pathways linked to their assessment pathways. In other cases, such as Finland, the UK, and Spain, HTA frameworks are decoupled from funding decisions or are used primarily to inform local procurement or pilot schemes.

From the perspective of developers, this fragmentation can translate into highly unpredictable and resource-intensive pathways to market. Duplicated evidence generation across countries can increase costs, while divergent timelines and criteria may delay or even prevent scaling across borders. Academic literature echoes these concerns. As Boers et al. (2025), Coder et al. (2024) Mezei et al. (2023) and Zrubka et al. (2024) emphasise the absence of a shared European understanding of what constitutes a DHT, and which technologies should be assessed. Divergent evidence requirements are highlighted by (Mezei *et al.*, 2023; Tarricone *et al.*, 2024), while fragmentation of reimbursement pathways is noted by (Van Kessel, Srivastava, *et al.*, 2023). Together, these studies underline how inconsistency in scope, criteria, and reimbursement undermines the predictability and efficiency of European HTA practices.

The findings underpinning H1 should be interpreted in light of the review scope. The mapping relied on a literature search with language restrictions and publicly accessible documentation. Countries may have well-functioning DHT markets or operational arrangements that are not described in the sources identified. The conclusion therefore reflects the documentation captured by the review rather than a definitive census of country practice. Nevertheless, the findings suggest that adaptation efforts for a HTA framework must go beyond the formal alignment of domains, but they must extend to harmonisation of interpretation of evidence standards and ideally integration with reimbursement. Without such convergence, developers will face disproportionate burdens, and valuable innovations may fail to achieve system-wide uptake. This creates opportunities for policy coordination and shared learning, which may be particularly relevant in the context of the forthcoming implementation of the European HTA-Regulation.

5.1.2 Hypothesis 2 (H2)

The second hypothesis explored whether the *barriers and challenges developers face stem from misalignments between current HTA practices and the characteristics of digital innovation* (H2a), and whether *these challenges affect SMEs disproportionately and vary by type of technology* (H2b). This is central to understand how current HTA and market access practices influence developers, and which existing practices are considered as challenges and barriers to developers.

Hypothesis 2 (a)

The findings as illustrated in Figure 4 strongly support H2a. A set of shared challenges and structural barriers were identified that hindered the market entry and implementation of DHTs in

Europe. Developers identified challenges and barriers as early as in the regulatory phase, including complex and fragmented approval procedures, country-specific interpretations of EU-level requirements (e.g. MDR, GDPR, EHDS), and high upfront certification costs. The evidence generation phase posed further challenges, as traditional methods such as RCTs were viewed as misaligned with the iterative nature and agile development cycles of digital tools. Developers noted that usability, technical performance and real-world adaptability were rarely captured in current evidence expectations. Infrastructure limitations, particularly in data access and interoperability, further restricted the implementation of RWE strategies. Market access pathways and HTA frameworks specific for DHTs remained largely non-existent in most countries, with DHT integration into clinical workflows and digital infrastructure posing particular barriers in system-wide implementation of DHTs. Reimbursement was characterised by long timelines, with only a few countries offering DHT-specific pathways. Finally, the absence of structured processes for re-assessment meant that iterative improvements in DHTs were not adequately captured, which developers perceived as a disincentive to continuous innovation and improvement.

These findings are echoed in the literature. Hendricks et al. (2018) emphasize that the lack of predictability in HTA systems directly impacts the investment and market entry strategies of developers, a sentiment mirrored by the participants in this study. Furthermore, the mismatch between static HTA assessment models and the iterative development cycles of DHTs identified in the results is supported by (Alami *et al.*, 2024; OECD, 2025) who argue that traditional pharmaceutical-oriented HTA pathways fail to accommodate the agile nature of digital innovation. The need for a transition from passive assessment to a more collaborative, early-engagement framework, as suggested by the developers' call for "proportionality and clarity", is a central theme in recent methodological critiques by Jiu et al. (2022) and Lantzsch et al. (2022) who advocate for stakeholder-inclusive innovation in HTA methods to reduce procedural uncertainty. Together, these findings and supporting literature underline that key challenges and barriers stem from limited and uneven institutionalisation of DHT specific market access pathways that generates high uncertainty for developers and that without institutional reform toward more adaptive and transparent evaluation, HTA remains a significant deterrent to the timely scaling of digital health solutions across Europe.

Hypothesis 2 (b)

Findings provide partial support for H2b (see Figure 4). Clear differences were observed between SMEs and larger companies, but only limited variation by technology type. Differences between SMEs and large industry players were visible in the way SMEs versus large industry companies navigate complex and lengthy certification, market access and reimbursement procedures. SMEs consistently described disproportionate burdens, particularly due to limited financial and organisational capacity to absorb the costs of certification, evidence generation, and lengthy reimbursement procedures. Many saw these barriers as existential threats, forcing them to delay or even abandon market entry. By contrast, large companies reported facing the same misalignments but were able to mitigate their effects through established regulatory teams, stronger financial reserves, and broader product portfolios. This "disproportionate burden" is echoed in peer-reviewed literature and several industry reports. Zah et al. (2022) highlights that current policy frameworks fail to account for the resource constraints of smaller innovators. Similarly, an EIT Health (2022) report notes that manufacturers, particularly those with roots in the software development community rather than traditional healthcare industries, face significant hurdles in planning and funding market access. Finally, the McKinsey Health Insitute, (2025) report confirms, that startups to divert a significant portion of their early-stage venture capital toward navigating fragmented regulatory frameworks rather than product R&D.

Technology-specific differences emerged only in certain areas. Mobile app developers advocated to place greater emphasis on usability, data protection and patient engagement in assessments, domains they felt were undervalued in current HTA frameworks. Telemedicine developers, identified system integration and organisational benefit assessment as central challenges, suggesting a need to incorporate these explicitly into assessment criteria for these types of technologies. AI developers raised additional concerns regarding the lack of clarity around algorithm validation, transparency requirements for training datasets, and evolving expectations around re-assessments, issues that are less pronounced in mobile health or telemedicine platforms. While generally describing similar challenges and barriers, these nuances illustrate technology-specific challenges but were less decisive than company size in shaping the severity of barriers. This aligns with "fit-for-purpose" evaluation frameworks emerging in literature. As highlighted by Alami et al. (2024), Mezei et al. (2025), OECD (2025), Segur-Ferrer et al. (2024), Tsiasiotis et al. (2025) and Spreafico et al. (2025) a "one-size-fits-all" HTA model acts as a structural deterrent because different technologies require distinct evidentiary focuses.

Overall, the results confirm H2a and partially confirm H2b. Misalignments between HTA practices and digital innovation characteristics are a primary source of barriers for all developers, confirming that HTA in its current form functions more as a constraint than an enabler of innovation. While challenges are shared across the sector, their impact is disproportionately severe for SMEs, threatening their sustainability and reducing diversity in the developer ecosystem. Differences by technology type were present but less decisive, suggesting that company size is the stronger determinant of vulnerability within the current European HTA landscape. These findings underline the need for proportionate, predictable, and innovation-sensitive HTA pathways that not only accommodate the iterative nature of digital health but also ensure that SMEs as key drivers of early-stage innovation are not excluded from the European digital health market.

5.1.3 Hypothesis 3 (H3)

Hypothesis 3 proposed that *adapting the HTA process by closing the gap between developer challenges and the characteristics of digital innovation will be perceived as enabler of innovation.* This assumption emerged directly from the findings of RQ1 and RQ2, which demonstrated that current HTA frameworks remain rooted in pharmaceutical traditions and are poorly aligned with the needs of DHT developers. Fragmented taxonomies, rigid evidence expectations, and long reimbursement timelines created uncertainty and hindered scaling, especially for SMEs. From this starting point, the question was whether recommendations grounded in developers' expressed needs could re-position HTA as an enabling instrument within Europe's digital health innovation ecosystem.

The gap analysis made it clear that developer challenges are not only methodological, but also systemic: a lack of proportionate assessment models, insufficient clarity on acceptable evidence, and limited mechanisms for re-assessment systematically constrained innovation. Literature argues that aligning HTA and reimbursement processes more closely with characteristics of digital health tools would remove a significant barrier for widespread technology uptake (Stern *et al.*, 2022; Van Kessel, Roman-Urrestarazu, *et al.*, 2023; Coder *et al.*, 2024; Tarricone *et al.*, 2024; Mezei *et al.*, 2025; Spreafico *et al.*, 2025). This systemic constraint is further evidenced by multi-stakeholder research including HTA agencies, policy makers, patients, clinicians, which highlights that current HTA methods lack the necessary flexibility to address the diverse and fast-evolving nature of DHTs (Tsiasiotis *et al.*, 2025). The recommendations developed in this research, such as harmonised evidence requirements, multi-phase assessments tied to the

lifecycle of DHTs, use of RWE, recognition of digital-specific value and earlier stakeholder involvement directly address these misalignments. If implemented, these reforms would reduce uncertainty, shorten time-to-market, and create clearer incentives for developers to invest in high-quality, interoperable, and secure technologies. Supportive measures such as early advice and access to guidance can reduce trial-and-error, increase transparency, and give smaller firms more confidence in the process. In this sense, HTA could evolve from being perceived as a barrier into an enabling policy instrument that stimulates innovation. Therefore, the results validated H3.

While adapting the HTA process to better align with digital innovation is a critical enabler, it is not a sufficient factor on its own for successful market uptake or clinical impact. Research indicates that implementation into routine care is affected by complex human and organisational factors. Specifically on acceptability and usability among patients, who may face barriers related to digital literacy, age or socioeconomic status and the endorsement of healthcare professionals (Ross *et al.*, 2016) (Gagnon *et al.*, 2012), regardless of its formal HTA status. This observation is consistent with the NASSS framework (Greenhalgh and Abimbola, 2019) which argues that digital health innovation is a "sociotechnical" process. It is also exemplified by recent data from Germany's DiGA program: only 12% of outpatient doctors and psychotherapists prescribed a DiGA and with the relatively low reach of prescriptions on few applications DiGA have not yet truly disrupted outpatient care in Germany (Gensorowsky *et al.*, 2024). Such dynamics are typical of emergent technologies but simultaneously highlight the need for addressing the broader system, including the physical infrastructure of health systems, the digital readiness of the workforce and the long-term engagement of end-users.

These findings also connect to wider debates in innovation policy. The policy mix perspective (Flanagan *et al.*, 2011; Borrás and Edquist, 2013) suggests that it is not individual instruments in isolation but their interaction that shapes innovation outcomes. The recommendations indicate that HTA could be reconceptualised not solely as a gatekeeping tool for resource allocation, but as a regulatory, incentive-based, and supportive instrument that influences developer behaviour and market dynamics. Seen together, these recommendations could place HTA within a wider innovation policy mix, where it interacts with existing policies such as the Medical Device Regulation (MDR), the HTA Regulation (HTA-R), the European Health Data Space (EHDS), and the Artificial Intelligence Act.

At the same time, the findings highlighted limits to this enabling role. Adaptation must be implemented in a way that it does not compromise patient safety, clinical effectiveness or the sustainability of health systems. The analysis therefore suggests that the future of DHT-specific HTA lies in striking a balance, avoiding over-regulation that may exclude SMEs by imposing unrealistic evidence burdens, while also avoiding under-regulation that risks unsafe or ineffective DHTs entering care. In this sense, HTA reform is not about lowering the bar, but about making the process fit-for-purpose for digital health. This requires a shift from viewing HTA purely as a gatekeeping tool towards positioning it as part of a deliberate policy mix that actively incentivises innovation while maintaining accountability and evidence-based decision-making.

Overall, the research demonstrates that by bridging the gaps between existing HTA practices and the characteristics of digital innovation, the proposed recommendations can reposition HTA as a potent enabler of digital health innovation. This enabling role, however, remains conditional as reforms must precisely balance flexibility and proportionality with the fundamental safeguarding of patient safety and added value. Therefore, HTA reform should be framed not merely as a methodological adaptation, but as an institutional innovation situated within the broader European policy mix. If implemented effectively, a reformed HTA framework could foster a more predictable and innovation-friendly environment for developers while ensuring that emerging technologies contribute to safe, effective, and sustainable health systems. Taken together, this underscores a dual aim for HTA reform: to facilitate timely innovation while maintaining rigorous assurance of patient safety and therapeutic value.

5.2 Limitations of the research

This study has limitations that are important to acknowledge. The scoping literature review was run with a title-restricted query and reliance on PubMed/Embase and therefore may have missed records indexed only in abstracts or in other databases (e.g., Scopus). Results of the literature review should therefore be interpreted with this in mind. A main limitation is the number of developers involved in the empirical research. While care was taken to include a diverse mix of company sizes, technology types and national contexts, both the survey and the focus group/interview sample was relatively small and not intended to be representative of the entire European digital health sector. Technology grouping between group comparisons relied on self-reporting and a priority rule to select the first listed type as primary category in case multiple types were relevant for the technology. Overlap across technology types (mobile app, telemedicine and AI) may persist despite the priority rule, and therefore comparisons should also

be interpreted cautiously. The aim was not to produce generalisable findings, but to identify recurring challenges and needs that could serve as a starting point for conceptualising a more innovation- and developer-friendly HTA framework.

Another limitation is the geographic scope of the study. Although several national systems were reviewed in depth, the research does not cover all European countries and cannot reflect the full diversity of national and institutional contexts. At the same time, the study was designed as an input into the EDiHTA project, where the framework developed based on these findings will be further validated across a broader range of countries and stakeholder groups, including additional developers, HTA bodies, policymakers, clinicians and patients. Moreover, the majority of developers included in the research had direct experience with pioneering DHT-specific HTA and reimbursement frameworks. As a result, insights from countries where DHT-specific HTA and reimbursement is less mature or less clearly linked to reimbursement can be underrepresented in the findings.

Another limitation relates to the stakeholder focus. The research focuses specifically on the perspective of technology developers. Other relevant stakeholder views, including those of HTA agencies, policy makers, payers, clinicians and patients are equally important and were not addressed in this research. However, the perspectives of other stakeholders are addressed in the wider EDiHTA project (Tsiasiotis *et al.*, 2025). While this limits the scope and the generatability of results in context of this dissertation, focusing on the developer perspective also allowed for a more detailed and grounded analysis of developer experiences, which are often underrepresented in HTA research.

5.3 Towards a balance in stakeholder interests

Focusing on developer experiences can risk creating an implicit contrast with regulatory and decision-making bodies. The intention of this thesis, however, is not to argue for weaker regulation or to position authorities as barriers to innovation. Rather, to point out the need and potential solution for a closer alignment between innovation dynamics and institutional responsibilities.

Regulation and HTA serve core public objectives, including patient safety, clinical effectiveness, equity and responsible allocation of resources. From the perspective of authorities, evidentiary standards are closely linked to accountability and risk management. Decisions on effectiveness

and safety must be transparent and defensible, particularly where DHTs influence clinical decision-making, care pathways, or patient behaviour. In such contexts, the insistence on high-quality evidence may reflect an institutional obligation to manage uncertainty rather than resistance to innovation. As highlighted in existing literature, regulatory systems often prioritise methodological robustness when faced with complex and potentially system-altering interventions (Drummond *et al.*, 2013; Unsworth *et al.*, 2021).

Perceptions of rigidity may also reflect institutional and procedural constraints. HTA agencies typically operate under formalised processes designed to ensure fairness, transparency, and consistency. These procedural safeguards may limit flexibility, even where there is recognition that digital innovation cycles differ from those of pharmaceuticals or conventional medical devices. In addition, DHTs often intersect with multiple regulatory domains, including medical device regulation, data protection frameworks such as GDPR, cybersecurity standards, and emerging AI governance. Navigating these overlapping regimes may incentivise cautious and standardised approaches. In this light, what is perceived by developers as inflexibility may, at least in part, reflect structural accountability and capacity constraints rather than unwillingness to adapt.

At the same time, the perspectives of patients and clinicians introduce an additional dimension that help reconcile developer expectations and regulatory caution. Adoption, sustained use, and real-world effectiveness depend on perceived usefulness, usability, trust and workflow integration. Technologies that satisfy formal regulatory requirements but fail to align with clinical practice or patient needs may generate limited impact. Early and meaningful involvement of end users has been associated with improved implementation outcomes and greater contextual relevance (Greenhalgh *et al.*, 2017; Van Velthoven *et al.*, 2018). Integrating patient and clinician perspectives into assessment processes may therefore reduce uncertainty and strengthen both the relevance and legitimacy of HTA decisions.

Interpreted through this broader institutional lens, the developer's perspective points towards the need for comprehensive institutional innovation for systematic integration of DHTs. The findings do not suggest that standards for safety and effectiveness should be lowered. Rather, they indicate that assessment processes may benefit from approaches that are proportionate to technological risk, sensitive to maturity level, and compatible with lifecycle-oriented evidence generation. By implementing concepts like the "virtuous policy cycle" proposed by Spreafico et al. (2025)

regulatory bodies can maintain methodological rigour while providing the predictability and agility required by innovators. Concepts such as adaptive HTA, staged evidence requirements, and dynamic re-assessment have been proposed in the literature as potential pathways to reconcile methodological rigor with innovation responsiveness (Henshall, Schuller, and HTAi Policy Forum, 2013; Brönneke *et al.*, 2023a, 2023b)(Henshall *et al.*, 2013; Brönneke *et al.*, 2023a, 2023b). By refining institutional processes without compromising core principles of safety, effectiveness, and equity, regulatory and HTA bodies may strengthen their capacity to govern digital health technologies in a rapidly evolving environment.

5.4 Practical implementation of results and future research

Beyond its academic relevance, the research has been designed with practical implementation in mind. The findings inform the conceptual development of a European Digital HTA (EDiHTA) framework, which aims to support the evaluation of DHTs in a more proportionate, transparent and innovation-friendly way. Next steps of the EDiHTA project will focus on in-depth development of HTA domains based on the second phase of the IHTAM framework (Jiu et a., 2022). The consortium will be developing evaluation criteria connected to the type and maturity level of DHTs, as well as validation of the framework in collaboration with a wide range of stakeholders, including health technology developers, HTA bodies, policymakers, patients, and healthcare professionals. These steps will involve structured feedback rounds, stakeholder workshops, and consensus-building methods, as well as piloting the framework on different types of DHTs (mHealth, telemedicine, AI) at different stages of their lifecycle. These pilots will help assess how the framework performs across varying risk levels, technology categories national contexts.

Validation activities will begin in late 2025 and extend through 2028, involving targeted use cases and pilot testing across mHealth, telemedicine and AI-based solutions. These pilots will assess the applicability of the framework across various risk classes and lifecycle stages, in different national contexts. They will also serve to test whether the recommendations presented in this thesis, such as multi-phase assessments based on lifecycle-phase of the DHT, integration of digital-related value assessment aspects and support material for can be translated into practical tools and procedures. This empirical testing will be supported by iterative feedback loops and consensus-building processes such as Delphi studies, expert panels, and stakeholder workshops, ensuring alignment with both regulatory feasibility and real-world developer needs.

In parallel to the technical and methodological development, the question of long-term sustainability and institutional anchoring of the framework remains central. Work is also ongoing to ensure that the final framework has a clear path to policy relevance. One of the intended routes for sustainability is through alignment with the evolving European HTA landscape, particularly the HTA-R. The recent establishment of the Digital Health Subgroup under the HTA Coordination Group presents a key opportunity in this regard (Tsiasiotis *et al.*, 2025). While the DHT specific HTA framework within EDiHTA is currently being developed as a voluntary and non-binding framework, its long-term utility depends on its ability to integrate into ongoing JCA activities of the HTA Coordination Group. For this purpose, dialogues are ongoing with national HTA bodies and EU institutions to position the framework as a supportive instrument that can enable methodological and institutional convergence without duplicating existing assessment procedures. The impact and interplay between other regulations including the proposal on the European Health Data Space, Data Act or the Artificial Intelligence Act are equally important but for now remain unclear.

Finally, the results of this research open several opportunities for future research. First, a deeper examination of national implementation challenges could be undertaken, particularly focusing on the operational readiness of HTA bodies to adopt dynamic, proportionate methods such as those proposed here. Further research could explore the role of ecosystem enablers, such as data infrastructure, reimbursement pathways for iterative innovations and regulatory expertise in shaping the success of DHT-specific HTA. Third, comparative studies between digital health regulation in Europe and other innovation-intensive regions (e.g. the US, Canada or Israel) could yield valuable insights into the institutional factors that facilitate or hinder agile assessment. Additionally, there is scope for longitudinal studies that track the impact of new assessment approaches on developer behaviour, market entry timelines and health system integration. Continued engagement with developers and other ecosystem stakeholder is essential to ensure that HTA systems can keep pace with digital transformation while remaining aligned with health system goals.

6 Conclusion

This dissertation has explored the challenges, needs and perspectives of DHT developers in navigating the fragmented HTA and market access landscape across Europe. By centring the analysis on DHT developers, it provides a perspective that has so far been underrepresented in HTA research and policy debates. While many prior studies have focused on methodological

refinements of HTA, this research demonstrated *that the key barrier to innovation lies not only in methodological detail, but in the deeper misalignment between current HTA processes and the characteristics of digital innovation.*

The findings suggest that HTA in its current form continues to act as a gatekeeper, shaping the environment in ways that constrain rather than support digital health innovation in the region. Developers consistently described unpredictable and resource-intensive assessment pathways, fragmented national requirements, and evidence standards misaligned with the iterative and user-centred nature of digital health. These barriers result in high uncertainty and delay the integration of promising technologies into health systems. From an innovation systems perspective, this also reflects a contradiction. According to the Triple Helix model, effective innovation systems require governments to act as facilitators, removing barriers, fostering knowledge exchange, and connecting industry and academia, rather than serving primarily as gatekeepers. While Europe has invested heavily in digital infrastructure, regulatory reform, and innovation funding, the bottleneck of HTA and reimbursement risks limiting the societal return on these investments. Unless HTA is adapted to be more innovation-responsive, the European digital health sector may fall behind competing global regions where market access frameworks are perceived as more predictable and innovation-friendly.

At the same time, the research underlines that enabling innovation cannot mean lowering standards of evidence or compromising the principles of equity, safety, and sustainability in health systems. The popular “fail fast and break things” approach often dominating the technology sector is unlikely to translate into healthcare, where the consequences of failure are effect not early adopters of consumer products but by patients and clinicians. In this context, patient safety and system integrity must remain paramount. The challenge is therefore to identify a middle ground where DHTs can enter markets more quickly and generate evidence proportionate to their maturity, while maintaining robust safeguards. This balance is critical to ensure that HTA does not merely become a facilitator of commercialisation but continues to serve its public mandate of protecting patients and supporting sustainable health systems.

From a DHT developer perspective, this carries important implications. While HTA processes must close the gap between innovation characteristics and evidence requirements, companies also bear responsibility for understanding the realities of European health systems. Developers should take the time to align their technologies with the digital health environment of the region

and to build the high-quality evidence that payers require. Therefore, success in Europe will depend not only on successful HTA reform as part of a policy mix, but also on the capacity of innovators to demonstrate real value within the diverse contexts of European healthcare.

HTA reforms based on the DHT lifecycle (e.g. preliminary assessments at early stages, re-assessment as real-world evidence is available) would not only better reflect the realities of digital innovation but also improve financial predictability of DHT solutions. By shortening timelines, reducing uncertainty, and avoiding duplication, HTA reform could address three key financial inefficiencies: time, uncertainty and waste of resources, without relaxing standards of safety or effectiveness. For investors, these iterative steps could also provide more reliable signals of value of a technology. Real-options thinking suggests that multi-stage assessments can improve the return profile of both companies and investments, by allowing staged commitments and reducing the risk of binary "all-or-nothing" decisions. In this way, better-aligned HTA processes would not only strengthen trust among regulators and health systems but also increase the attractiveness of the European digital health sector for private capital.

These conclusions contribute to the conceptual foundations and practical direction of HTA reform in Europe and offer a roadmap for fostering a more aligned, innovation-ready ecosystem for digital health. This framing moves beyond the view of HTA as a static evaluative tool and instead conceptualises it as a dynamic policy instrument that interacts with regulatory requirements, reimbursement rules, data infrastructures, and industrial policies. Within such a policy mix, HTA has the potential to evolve from a barrier to a driver of digital innovation. The recommendations developed in this research aim to contribute to this rebalancing by aligning evidence requirements with the characteristics of digital technologies, improving predictability for developers, and ultimately strengthening Europe's capacity to integrate safe, effective, and innovative solutions into health systems. By adapting HTA to the realities of digital innovation, Europe can create a more innovation-friendly environment that reduces uncertainty for developers, encourages responsible investment, and accelerates access to high-quality digital solutions.

Ultimately, this dissertation argues that the question is not whether HTA should adapt, but how quickly and effectively it can do so. If Europe succeeds in repositioning HTA as part of a balanced innovation policy mix, and if developers take on the responsibility of producing robust, context-sensitive evidence, the result will be a more predictable, trustworthy and innovation-

ready ecosystem, one that supports both the scaling of digital health technologies and their safe integration into European health systems.

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8 Appendix

8.1 Appendix A - Survey

EDiHTA: The first European Digital HTA framework co-created by all stakeholders along the value chain.

EDiHTA stands for the first European Digital Health Technology Assessment framework co-created by all stakeholders along the value chain – and is the title of a new research and innovation project recently funded with 8 million euros under the EU's Horizon Europe framework. Coordinated by the Università Cattolica del Sacro Cuore (Rome, Italy) and led by Prof. Americo Cicchetti, the project successfully commenced its mission to develop a new, digital Health Technology Assessment (HTA) framework for Europe's health ecosystem on January 1, 2024.

Digital Health Technologies: (Un)-locked potential

In a world where health systems worldwide are under constant pressure to provide high-quality services, digital health technologies (DHTs) like telemedicine, mHealth apps or AI-based tools emerge as potential game-changers.

Digital health technologies are expected to improve both the quality and delivery of healthcare services while ensuring the sustainability of Europe's healthcare systems. DHTs are also able to collect real-world data and evidence relevant for decision makers.

However, existing Health Technology Assessment methodologies are unable to capture the real added value of DHTs. The implementation of digital health technologies implies new methodological challenges to the standardisation of assessment criteria.

If existing Health Technology Assessment methodologies remain not harmonised and interoperable at EU level, they are unable to capture the real added value of DHTs. This is what EDiHTA aims to solve to ultimately unlock the potential of DHTs for Europe's healthcare landscape.

EDiHTA: Innovative Framework for DHT Assessment

EDiHTA aims to be the first digital, flexible, inclusive, validated and ready-for-use European HTA framework, allowing the assessment of different DHTs (e.g. telemedicine, mApps, AI) at different TRLs, territorial levels (national, regional and local) and perspectives (e.g. payer, society, hospital). ***Implementing a co-creation approach, all relevant stakeholders will contribute to its design, development and validation.*** The digital framework will be piloted in real healthcare settings in five major European hospitals and through an open piloting scheme with European DHT developers.

Survey

By participating in this questionnaire, you are helping to identify the most critical factors in the development of new digital health technologies from a technology developer point of view. Your insights are invaluable to advancing the field and ensuring that new assessment methodologies meet the needs of technology developers.

Note: Relevance of each factor should be established on a Likert scale ranging from 1 = Not at all important/relevant; 2 = Minimally important/relevant, 3 = Slightly important/relevant; 4 = Somewhat important/relevant; 5 = Moderately important/relevant; 6 = Quite

important/relevant; 7 = Very important/relevant; 8 = Highly important/relevant; 9 = Extremely important/relevant.

A. Name of company
B. Country of main market
C. Established (year)
D. Type of technology (if multiple types e.g. mobile app with AI, indicate in order of relevance)
    1. Mobile App
    2. Telemedicine
    3. AI
    4. Robot
    5. Other (please specify)
E. Is there a department of evaluation/assessment (HTA) or Market Access within your organisation?
F. What is the main Therapeutic Area of interest for your company? If more than one please specify the first three.
G. Do you develop all the parts of the technology in house?

1. **Clinical need within target population**
   How important/relevant is the clinical need and target population in your decision to develop the Technology?
2. **Size of target population**
   How important/relevant is the size of the target population in your decision to develop the Technology?
3. **Regulatory compliance**
   How important/relevant are regulatory compliance requirements (besides GDPR) in your development strategy?
4. **Time to develop the DHT – Complexity**
   How important/relevant is the complexity and time required in your decision to develop the digital health technology?
5. **Development Costs**
   How important/relevant are the initial costs to your decision to develop a new digital health technology?
    - Device/Hardware maintenance (e.g. shipping costs to and from maintenance location, spare parts)
    - Software development / bug maintenance
    - Personnel needs (quantity and training)
    - Other (please specify)
6. **Maintenance costs**
   How important/relevant is ongoing maintenance costs in your decision to develop a new digital health technology?
    - Device/Hardware maintenance (e.g. shipping costs to and from maintenance location, spare parts)
    - Software development / bug maintenance
    - (quantity and training)
    - Other (please specify)
7. **Having a comparator (SoC)**
   How important/relevant is having a clear standard of care (SoC) comparator when developing a new digital health technology?

8. **Technical characteristics**
   How important/relevant is the adaptability of the technology for future development when initially considering the development strategy of the technology?
9. **Patient safety**
   How important/relevant is ensuring patient safety during the use of the technology?
   a. In the development phase of the technology
   b. In the use of the technology phase
10. **Privacy and security**
    How important/relevant is privacy and security of the end user of the technology concerns you before developing the technology**?**
11. **Improvement in clinical outcomes**
    How important/relevant are improvements in clinical outcomes for developing a new technology?
    - Direct impact on Clinical outcomes
    - Integration of care
    - Continuity of care (long-term)
    - Type of clinical improvement evidence provided using the technology
12. **Readiness of health system (usability and acceptance)**
    How important/relevant is the readiness of health systems in the development of your health technology?
13. **Access market timing**
    How important/relevant is the market access for your digital health technology?
14. **HTA process (in target market)**
    How important/relevant is the Health Technology Assessment (HTA) process in the target market for your development decisions? /
15. **HTA process (in target market)**
    Do you look into the HTA process before making development decisions (Yes/No)?
16. **Pricing and reimbursement process (in target market)**
    How important/relevant are reimbursement and market access policies in the target market for your digital health technology development?
17. **Expected Return of Investment (ROI)**
    How important/relevant is the expected return on investment (ROI) in your development decisions for digital health technologies?
18. **Readiness of patients (usability and acceptance, adherence)**
    How important/relevant is the readiness of patients in the development of your health technology?
    - Usability (user experience) of solutions for your target population
    - Acceptance and willingness to use the solution for your target population
    - Expected adherence for your target population
19. **Stakeholder involvement in the development phase**
    How important/relevant is early involvement of patients/caregivers in the development of the technology?
    How important/relevant is early involvement of clinicians/healthcare providers in the development of the technology?
20. **Data ownership**
    How important/relevant is data ownership in your approach to developing new digital health technologies?
21. **Data privacy (GDPR)**
    How important/relevant are data privacy concerns, including GDPR compliance, in your development process?
22. **Final comments**

Do you have any additional comments or considerations that are important to you when developing a new digital health technology (open question)?

8.2 Appendix B - Focus Group and Interview protocol

Introduction of focus group facilitators & participants: Name, Surname, Institution, Role (5 mins)
Introduction of EDiHTA project and main results of survey (10 mins)

Challenges & priorities with market access & reimbursement of DHTs

- What are your key challenges when entering one or multiple European market(s)? Do you have challenges linked specifically to access to reimbursement?
- What is your approach to market access & reimbursement when entering more European markets at the same time?
- Do you consider assessment of DHTs during different phases of technology development? (e.g. early phase of development, late phase of development, post-market phase)
  How can the assessment framework capture this? How about evidence requirements?
- Lack of transparency and predictability on evidence generation requirements for regulatory approval and funding/ reimbursement decision-making. How can we take this into account when desiginging an innovation friendly assessment framework?

Challenges with specific HTA domains and processes

- What are the key challenges you face with readiness of health system & target population to implement a technology?
- What are the key challenges you face with privacy, data security and data ownership?
- Patient centric approach for developers? Is there a success story or is not sustainable?
- Is continuous evidence and post implementation monitoring of the DHTs something you could be of support?
- Any additional comments or considerations that are important to you when developing a new digital health technology?

Vision & Future

- How do you see the future in terms of a common market for DHTs?
- Do you see a common pan-European assessment approach being beneficial to you?
  What would be the best value for you?
- Following the response to the survey and today's discussion;
  What would you expect from the EDiHTA project to provide of value to you?
  What is the main priority(ies) for you? What kind of information would you like to have through the EDiHTA platform?
- Sustainability of the EdiHTA framework?

Do you have any further comments?

9 Scientific publications related to the thesis

1) **Mezei, F**., Tsiasiotis, E., Basile, M., Sciomenta, I., Calosci, E. M., Antonini, D., Lukacs, A., Di Bidino, R., Cicchetti, A., & Sacchini, D. (2025). Shaping the Future of DHT Assessment: Insights on Industry Challenges, Developer Needs, and a Harmonized, European HTA Framework. *Journal of Market Access & Health Policy*, *13*(3), 46 https://doi.org/10.3390/jmahp13030046

2) **Mezei, F.,** Dózsa K., (2022) Digitális egészségügyi technológiák értékelése : Diabétesz applikációk Németországban = Assessment of digital health technologies – Diabetes applications in Germany. IME: INFORMATIKA ÉS MENEDZSMENT AZ EGÉSZSÉGÜGYBEN, 21 (2). pp. 64-68. ISSN 1588-6387 http://doi.org/10.53020/IME-2022-207

3) **Mezei, F.,** Horváth, K., Pálfi, M., Lovas, K., Ádám, I., & Túri, G. (2023) International practices in health technology assessment and public financing of digital health technologies: Recommendations for Hungary. Frontiers in Public Health, 11, 1197949. https://doi.org/10.3389/fpubh.2023.1197949

4) Tsiasiotis, E., **Mezei, F**., Di Bidino, R., Basile, M., Battaglia, L., Strammiello, V., Kidholm, K., Oortwijn, W., Cicchetti, A., & Sacchini, D. (2025). Toward a Harmonized Health Technology Assessment Framework for Digital Health Technologies in Europe. Value in health : The journal of the International Society for Pharmacoeconomics and Outcomes Research, S1098-3015(25)06192-3. https://doi.org/10.1016/j.jval.2025.12.004

5) Boers, M., Rochereau, A., Stuwe, L., Miguel, L. S., Klucken, J., **Mezei, F**., ... & Zohar, S. (2025). Classification grid and evidence matrix for evaluating digital medical devices under the European union landscape. npj Digital Medicine, 8(1), 1-10. https://doi.org/10.1038/s41746-025-01697-w

6) Tsiasiotis, E., **Mezei, F**., Basile, M., Calosci, E. M., Sciomenta, I, Sacchini, D., & Di Bidino, R. (*Manuscript under preparation*). A policy perspective on the need for a complementary HTA framework for digital health technologies.

7) Gulácsi, L., Hölgyesi, Á., **Mezei, F**., Jónás, N., Zrubka, Z., & Péntek, M. (*Manuscript under preparation*). Eight points to consider for the health economic evaluation of digital medical devices.

8) Poster: **Mezei, F.** (2021) First insights into the new reimbursment route of digital health applications (DIGAs) in Germany (2021). Hungarian Health Economic Society (META) Congress 2021, Budapest.

9) Poster: **Mezei, F.** (2025) Digitális orvostechnikai eszközök értékelési gyakorlatainak harmonizációja Európában. Hungarian Health Economic Society (META) Congress 2025, Budapest.

10 Additional scientific publications

10) Wennekes, M.D., Almási, T., Eilers, R., **Mezei, F**., Petykó, Z. I., Timen, A., & Vokó, Z. (2024). Effectiveness of educational interventions for healthcare workers on vaccination dialogue with older adults: a systematic review. Arch Public Health, 82(34) https://doi.org/10.1186/s13690-024-01260-1

11) Makovec, U. N., Goetzinger, C., Ribaut, J., Barnestein-Fonseca, P., Haupenthal, F., Herdeiro, M. T., ... & Dima, A. L. (2022). Developing a medication adherence technologies repository: proposed structure and protocol for an online real-time Delphi study. BMJ open, 12(4), e059674. https://doi.org/10.1136/bmjopen-2021-059674

12) Dózsa,K., **Mezei, F**., és Kalmár, István és Sinkó, Eszter és Joó, Tamás (2022) Egészségügyi struktúraváltást támogató, bizonyíték alapú szolgáltatásfejlesztések bemutatása a praxisközösségi modellprogramok (2013-2020) működésének tapasztalatai alapján. IME: INTERDISZCIPLINÁRIS MAGYAR EGÉSZSÉGÜGY / INFORMATIKA ÉS MENEDZSMENT AZ EGÉSZSÉGÜGYBEN, 21 (3). pp. 3-15. ISSN 1588-6387 http://doi.org/10.53020/IME-2022-301

13) Olah, I., Dózsa, K., Boldog, Zs., Rosta L., Kalmár I., **Mezei, F.,** Kempler, L. (2022) Diabetes gondozási program a háziorvosi gyakorlatban. A cukorbetegek klinikai irányelven alapuló krónikus gondozási programjának bemutatása. Diabetologica Hungarica https://doi.org/10.24121/dh.2022.16

14) Dózsa, K., **Mezei, F**., Tóth, T., Perjés, Á, & Pollner, P. (2021). Countrywide survey on utilization of medical devices by GPs in Hungary: Advantages of the cluster-practice model. Primary Health Care Research & Development, 22, E34. doi:10.1017/S1463423621000372

15) Dózsa, K., **Mezei, F.,** Kalmár I. (2020) A tűzoltás ideje lejárt: Korszerű krónikus beteg-gondozási programok bevezetésének indokoltsága a magyar alapellátásban. Medical Online. Available online

11 Individual contributions to the research

Throughout the course of this research I was actively involved in all phases and took the lead on the key phases of the doctoral research. While part of this research was executed with collaborators in the wider context of the EDiHTA project, my individual contributions were as follows:

- **Development of literature search strategies**: Independently designed the search strings for the main bibliographic databases, ensuring that the chosen keywords and Boolean operators comprehensively reflected the research question.
- **Pilot literature searches**: Conducted pilot searches in the main databases to refine the search strategies and confirm their relevance and sensitivity.
- **Identification of grey literature sources**: Identified relevant grey literature repositories, formulated specific search terms for these sources, and executed the searches to capture non-peer reviewed materials.
- **Final search execution and data management**: Ran the final literature search, exported the bibliographic records, performed automated deduplication to ensure a clean dataset for screening.
- **Quantitative analysis of questionnaire**: I conducted descriptive and comparative statistical analyses of the survey data, examining response patterns, identifying trends, and exploring potential differences across company size, technology type, and geographical focus.
- **Organising, grouping and scheduling focus group and interviews**: I coordinated the recruitment and scheduling of over 30 participants from diverse organisational backgrounds and countries. This involved liaising with potential participants, arranging suitable time slots across multiple time zones, preparing invitation materials, and ensuring all participants received the necessary briefing documents in advance.
- **Focus group and protocol development:** I was responsible for drafting the first version of the focus group and interview protocols, as well as finalising the protocol after collecting input from colleagues
- **Moderating focus group and leading interviews**: I was responsible for moderating the focus groups and leading discussion throughout the interviews with developers
- **Documentation and validation of interviews and focus groups**: I took detailed notes during focus groups and interviews, summarising discussions and incorporating feedback into the evolving versions of the transcripts. I was also responsible for collecting written validation from participants via email.

- **Qualitative data processing**: I processed the transcripts of the focus groups and interviews, ensuring the accuracy and completeness of the qualitative data for subsequent analysis.
- **Data analysis and interpretation**: I carried out initial thematic analysis of the data in line with the study framework. I identified and refined themes, compared patterns across stakeholder types and company sizes and interpreted findings in light of the survey results and relevant literature.
- **Manusript development**: I was responsible for drafting the first versions of the first (Mezei and Dózsa, 2022), the second (Mezei et al., 2023) and third (Mezei et al., 2025) manuscripts as well as the posters (Mezei, 2021 and Mezei, 2025), including the textual content and the preparation of figures and tables, and finalising them based on inputs of co-authors.

The following contributions were executed as part of a research team:

- **Screening and analysis of DHT-specific HTA frameworks:** Support in identification through the literature review and analyis per types of technologies assessed, methodology (domains assessed) and connection to public reimbursement pathways
- **Development of questionnaire:** Support in the design of the survey instrument, contributing to the formulation of questions and response formats to ensure alignment with the study objectives and clarity for respondents.
- **Recruitment of participants:** Support in identification and engagement of eligible participants from relevant sources, ensuring diversity in geography, company size and technology type.
- **Validation of focus group and interview protocols:** Reviewed feedback on the draft protocols, ensuring that the content was coherent, comprehensive and consistent with the research.
- **Formulating recommendations based on findings:** Contributed to the development of actionable recommendations derived from the analysis of survey, interview, and focus group data, ensuring they reflected both evidence and practical applicability.
- **Conceptual and visual presentation of figures:** Contributed with first drafts on the figures presenting results, with support in conceptual and visual improvements.

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