ÓBUDAI EGYETEM
ÓBUDA UNIVERSITY

THESIS BOOKLET

MEZEI FRUZSINA

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

Supervisors:

Dr. habil. Zrubka Zsombor János
Prof. Dr. Fogarasi József

INNOVATION MANAGEMENT DOCTORAL SCHOOL

BUDAPEST, 2026

TABLE OF CONTENTS

1. Background

The rapid evolution of digital health technologies (DHTs) presents significant opportunities for healthcare systems worldwide. These technologies, including mobile health applications, telemedicine, digital therapeutics (DTx), and artificial intelligence (AI) solutions are increasingly recognised for their potential to transform disease management, enhance patient outcomes, and improve the efficiency of healthcare delivery. However, unlike pharmaceuticals and medical devices that follow well-established regulatory, health technology assessment (HTA) and reimbursement frameworks, the market access pathways applicable to DHTs are often not clearly defined or are still emerging in some countries. Their variety, broad range of use cases, software-driven iterative nature and user-centricity pose significant challenges for conventional value assessment models, which may limit their integration into health systems and delay access by healthcare professionals and patients.

In response, European countries are taking a variety of approaches to better capture the unique attributes of DHTs and integrate them into their national healthcare systems. Germany, France, and Belgium have introduced structured fast-track pathways coupled with reimbursement, enabling certain categories of DHTs to be more systematically integrated into healthcare. Finland, Spain, and the United Kingdom have developed dedicated assessment methodologies to guide adoption and procurement. Despite these developments, most EU countries continue to rely on traditional HTA frameworks, which are often ill-suited to assess digital-specific characteristics such as usability, interoperability, cybersecurity, and real-world performance. At European level, the HTA Regulation introduces joint clinical assessments (JCA) for medicines and high-risk devices but excludes most DHTs. Complementary initiatives such as the EvaluDMD Taskforce, EDiHTA, AssessDHT projects, and the Medical Device Regulation (MDR), European Health Data Space (EHDS), AI-Act are emerging to bridge gaps and harmonise approaches.

Health technology 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. If they perceive existing market access pathways as misaligned, unviable or not transparent, 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. This underscores the importance of understanding how system-level inefficiencies translate into practical barriers for developers. At the same time, the role of HTA must be understood within Europe's wider innovation system. Instead of acting as a barrier, it should function as a facilitator of knowledge exchange, collaboration, and trust between policymakers, industry, and academia. Within this perspective, EU-level strategies such as the Digital Single Market highlight the importance of reducing fragmentation and creating enabling conditions for innovation across borders. While Europe is heavily investing in digital infrastructure, regulatory reform, and innovation funding, the bottleneck of HTA and reimbursement risks limiting the return on investments (ROI) in the digital health sector.

By placing developer perspectives at the centre, this doctoral thesis aims to contribute to a dimension often underrepresented in HTA research and policy debates. Their insights not only reveal practical barriers in navigating current systems but also point to how HTA could evolve into a more dynamic and innovation-supportive policy tool. This perspective may help reframe HTA as an integral part of Europe's innovation agenda, supporting both competitiveness and the safe, effective, and sustainable integration of digital health technologies into health systems.

2. Objectives

The doctoral research aims to identify key barriers, challenges 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 generate knowledge that can support the future direction of HTA practices around DHTs in the European region.

3. Methods

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.

To address RQ1, a scoping literature review 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. 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. 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. The literature review was performed according to the PRISMA-ScR guideline, specifying the search strategy, the eligibility criteria, the selection of sources of evidence, and the method of the analysis.

Following the literature review, a survey was developed and distributed among DHT developers across Europe to address RQ2. The survey was distributed to international health industry players and start-ups/SMEs through conferences (e.g., HIMSS Europe 2024), networking events, social media, and EDiHTA consortium partner networks between June and September 2024 to understand what factors influence the decisions around the development of

a DHT. In exploring the priorities of digital health technology developers, the developers shared information regarding their company and background and rated the importance of various aspects for market access and reimbursement on a Likert scale from 1 to 9. Survey responses were followed up with focus groups and interviews with participating technology developers to validate and get in-depth insights on the findings. A standardized protocol was developed for both focus groups and interviews based on the International Health Technology Assessment Model (IHTAM) which guided participants through a reflective and forward-looking process. This approach allowed flexibility for discussions to cover various aspects and types of technologies.

Finally, RQ3 was addressed through an expert workshop and thematic analysis for formulation and analysis of recommendations for new HTA process specific for DHTs. 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.

To ensure the transparency of the research presented in the dissertation, Table 1 provides a summary of the proposed hypothesis, related research questions, objectives and methods discussed in previous chapters as well as the results of the research.

Table 1. Summary of research questions, objectives, methods, hypothesis and corresponding results presented in the dissertation

	Research Question	**Objective**	**Methodology**	**Hypothesis**	**Results**
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	H1. validated
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.	H2. (a) validated, H2. (b) partially validated
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	H3. validated

4. New Scientific Results

4.1. International practices of DHT-specific HTA

The literature review mapped the current landscape of HTA and reimbursement frameworks for digital health technologies (DHTs) across Europe, based on 70 included sources. The analysis revealed a small but growing number of DHT-specific frameworks (n=9) developed across seven countries: Germany, France, Belgium, Spain, Finland, the United Kingdom, and Scotland (Table 2). These initiatives vary widely in scope, the types of technologies assessed, methodological criteria, and their formal connection to reimbursement, confirming that institutionalisation of DHT-specific HTA in Europe remains fragmented and uneven.

Germany, France and Belgium have taken the most comprehensive steps, creating fast-track pathways that combine conditional reimbursement with requirements for subsequent real-world evidence generation. The DiGA and DiPA Fast-Tracks in Germany, and France's LATM and PECAN models, illustrate an emerging policy shift towards multi-phase assessments that enable earlier access while mandating follow-up validation. Belgium's mHealthBelgium framework similarly links assessment stages to reimbursement eligibility but places stronger emphasis on interoperability and system integration. By contrast, Finland's Digi-HTA, Spain's AQuAS framework, and Scotland's adapted HTA model primarily serve local procurement and pilot-based rollouts rather than centralised financing. The UK's Evidence Standards Framework provides clear guidance on proportionate evidence requirements but is not tied to reimbursement decisions.

The scope of technologies covered in the frameworks differs substantially. While some frameworks focus on CE-marked, patient-facing applications, others include broader categories such as AI tools, robotics, and system-level applications. This inconsistency is mirrored in the assessment criteria applied. 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. 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.

Overall, the analysis confirms that while many countries are adapting HTA processes to digital health, approaches vary widely in scope, methodology, and funding integration. Only Germany, France, and Belgium offer institutionalised reimbursement mechanisms, while others rely on local pilots or procurement. This lack of harmonisation complicates multi-country strategies for developers and reinforces the need for more predictable, proportionate, and coordinated pathways across Europe.

Table 2. List of DHT-specific HTA frameworks
Presented 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 reference framework for remote medical monitoring	yes
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

4.2. Challenges and needs of technology developers

Perspectives from 31 unique DHT companies (20 companies in the survey, 29 companies in the qualitative phase, and 16 companies only participating in the interview phase) (see Table 3), spanning startups, and well-established international firms across 10 European markets shed light on the needs of developers.

Table 3. 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	mHealth, Telemed	Austria	2015
Focus Group: Telemed	Yes	Telemed, AI	Ukraine, Germany	2019
Focus Group: AI	Yes	AI	US	2002
Focus Group: AI	Yes	mHealth, AI	Poland	2021

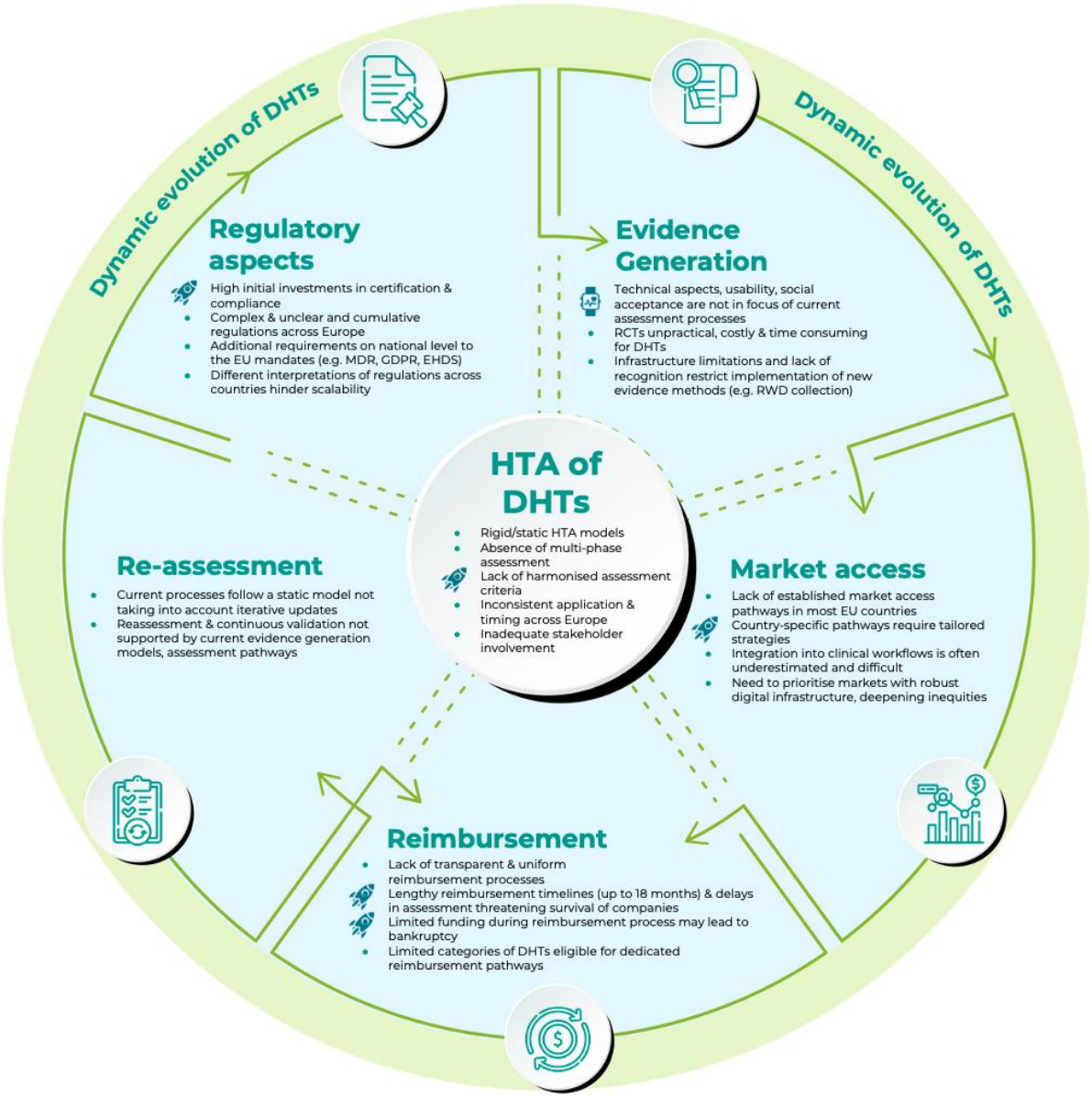
Focus Group: AI	No	AI	France	2020
Focus Group: Mixed	No	mHealth, Telemed	Finland	2020
Focus Group: Mixed	No	Robotics	Finland	2008
Focus Group: Mixed	No	mHealth	Finland	2020
Focus Group: Mixed	Yes	mHealth, Telemed	France, Germany, UK	2000
Focus Group: Mixed	Yes	mHealth, AI	Austria	2019
Focus Group: Mixed	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

Findings confirm that technology developers encounter substantial challenges across the full lifecycle of DHTs. These challenges cluster around six interrelated domains: regulatory aspects, evidence generation, market access, reimbursement, re-assessment, and the overarching design of HTA processes.

Regulatory pathways remain complex and fragmented, with varying national interpretations of EU-level rules such as the MDR, GDPR, and EHDS, leading to high upfront costs and limited scalability, especially for SMEs. Evidence generation poses further barriers, as traditional reliance on RCTs is often impractical for iteratively developed technologies. Developers highlighted that critical aspects such as usability, interoperability, and real-world adaptability are rarely prioritised in current assessments, while limited data infrastructure constrains the use of real-world evidence.

Market access and reimbursement pathways are similarly fragmented. Dedicated DHT-specific routes are lacking in most countries, resulting in long, opaque procedures that can extend up to 18 months, threatening the survival of smaller firms. Integration into clinical workflows and health system infrastructure remains uneven, with developers often favouring markets with stronger digital capacity, thereby risking inequities across regions. And finally, current HTA and reassessment processes were described as rigid and poorly adapted to continuous technological updates. Developers stressed the need for harmonised, transparent, and lifecycle-sensitive approaches that enable proportionate evidence requirements without compromising safety or sustainability. Importantly, their demand is not for weaker regulation but for frameworks that are predictable, adaptive, and supportive of innovation.

Figure 1. 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 (m-health, telemedicine, AI) were observed are marked with a smartwatch icon.



4.3. Recommendations for DHT-specific HTA

The findings from the gap analysis and developer perspectives point to several critical priorities that a DHT-specific HTA framework should address. These recommendations aim to reduce systemic inefficiencies, better align HTA with the realities of digital innovation, and provide developers with clearer, more predictable pathways to market access and reimbursement. The proposed framework is not intended to capture every possible developer need, but rather consolidates the most pressing priorities into six interrelated areas:

- **Harmonisation of taxonomy and evidence requirements across countries**, supported by a single access point for DHT-specific guidance. This would reduce

duplication, enhance consistency, and simplify navigation for developers targeting multiple markets.

- **Multi-phase assessment tied to the lifecycle of DHTs**, allowing earlier access under conditional approval, with follow-up reassessments based on new data. This structure would better reflect the iterative nature of digital innovation.
- **Recognition of digital-specific value dimensions in assessments**, such as usability, interoperability, workflow integration, and patient engagement, which are often overlooked in traditional HTA approaches.
- **Systematic integration of RWE** into assessment processes, enabling continuous validation of effectiveness, safety, and user experience in real-world settings.
- **Earlier and more structured stakeholder involvement**, including scientific advice and pre-submission consultations, to support developers in aligning evidence plans with HTA expectations.
- **Improved access to supporting materials for developers**, such as repositories of past HTA cases, methodological guidance, and training resources, which could increase transparency and reduce uncertainty in evidence preparation.

Together, these recommendations highlight a shift towards a more adaptive, proportionate, and innovation-responsive HTA framework. By reducing administrative burdens, providing clearer guidance, and recognising the unique characteristics of digital health, such an approach could reposition HTA as an enabler rather than a barrier to innovation, while ensuring that patient safety and system sustainability remain safeguarded.

Table 3. 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

4.4. Thesis and 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 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. The research proposes six concrete recommendations that support the development of an adaptive HTA frameworks for DHTs. The proposals aim to increase the responsiveness, transparency, and usability of HTA frameworks, particularly for smaller developers navigating complex systems.

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. Practical implementation of results

Beyond its academic relevance, the findings inform the conceptual development of a HTA framework, which aims to support more predictable, transparent and innovation-friendly access pathways for DHTs. Results of this research will be implemented by the EDiHTA project, where next steps will focus on development of HTA domains and timelines, as well as connecting evidence criteria to type and maturity level of DHTs. Developer perspectives, examined in the 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. Following the development phase, validation of the framework takes place in collaboration with a wide range of stakeholders, including health technology developers, HTA bodies, policymakers, patients, and healthcare professionals.

In parallel to the technical and methodological development, the question of long-term sustainability and institutional anchoring of the framework remains central. 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 sub-group under the HTA Coordination Group presents a key opportunity in this regard. While the HTA framework developed under EDiHTA is currently 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.

6. Conclusions

Findings underscore the need for a standardized HTA methodology that aligns with the realities faced by technology developers in Europe. First, the simplification, clarification, and harmonization of regulatory and Health Technology Assessment (HTA) requirements are essential to reducing administrative burdens and accelerating market access and reimbursement pathways. A structured approach to linking assessment requirements with specific technology types could further enhance transparency and efficiency. Additionally, a multi-phase assessment model that integrates real-world evidence (RWE) into evaluations is crucial. Enabling digital health solutions to be assessed at different development stages with continuous data collection for adaptive (re-)assessment would facilitate a more dynamic and evidence-driven regulatory process. Financial sustainability remains a pressing concern, particularly for startups and SMEs, emphasizing the need for tailored funding opportunities to support data collection, clinical validation, compliance, and reimbursement. Finally, promoting transparency through a public HTA case study repository could serve as a valuable reference for developers, offering insights into study designs, sample sizes, key outcomes, and best practices of already conducted HTA processes.

The foundational insights retrieved in this research will guide the iterative development and conceptualization of the EDiHTA framework, ensuring its sustainability and relevance in a dynamic digital health ecosystem. Rather than acting solely as a gatekeeper, HTA must evolve into a facilitator that helps connect state, industry, and academia, supports knowledge flows, and contributes to the EU's broader ambition of a Digital Single Market. Achieving this requires balance: avoiding over-regulation that risks blocking SMEs with unrealistic demands, while also preventing under-regulation that could allow unsafe or ineffective technologies to enter care. A fit-for-purpose, DHT-specific HTA framework can help close this gap, supporting developers in bringing trusted innovations to market and contributing to Europe's strategic goals of fostering a competitive, innovation-driven, and patient-centred digital health environment.

7. Scientific publications by the author

7.1. 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.,** 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

3) **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

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.

7.2. 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