

Themed Section: Digital Health Technologies

Toward a Harmonized Health Technology Assessment Framework for Digital Health Technologies in Europe

Emmanouil Tsiasiotis, MPH, Fruzsina Mezei, MSc, Rossella Di Bidino, PhD, Michele Basile, MSc, Livio Battaglia, MSc, Valentina Strammello, MSc, Kristian Kidholm, PhD, Wija Oortwijn, PhD, Americo Cicchetti, PhD, Dario Sacchini, PhD

ABSTRACT

Objectives: The increasing use of digital health technologies (DHTs) in Europe presents opportunities and challenges. Although DHTs could enhance care delivery and health outcomes, existing health technology assessment (HTA) methods often lack flexibility to address their diverse, fast-evolving nature. This article explores the perspectives of 5 stakeholder groups—policy makers, HTA agencies, technology developers, healthcare providers, and patients—regarding the development of a harmonized HTA framework for DHTs within the Horizon Europe funded European Digital Health Technology Assessment (EDiHTA) project.

Methods: Findings are drawn from mixed-method research, including stakeholder surveys, interviews and focus groups with 97 stakeholders across European countries. The analysis of the data was performed per each stakeholder group through thematic analysis to identify points of consensus before identifying needs and requirements across stakeholders, relevant to the development of EDiHTA, using the Innovation Health Technology Assessment Methods framework.

Results: Results from 8 focus groups and more than 45 interviews are presented concentrating on 5 main themes. The emerging themes focus on the need for harmonization of HTA methods related to DHTs, the current characteristics of DHTs that are most highly valued, the importance of multistakeholder collaboration, the principles of a concept design for EDiHTA framework, and the discussion on the most relevant domains and criteria to be considered.

Conclusions: Stakeholders agreed that a harmonized HTA framework is needed; however, differences persist regarding timing and flexibility of evaluation, evidence types, and stakeholder involvement. The EDiHTA project will address differences through framework piloting, supported by multistakeholder workshops and expert advisory groups.

Keywords: digital health technologies, EDiHTA project, evaluation, health technology assessment, stakeholder perspectives.

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Highlights

- The article addresses the lack of harmonized health technology assessment (HTA) methods for evaluating digital health technologies (DHTs) across Europe.
- Findings highlight broad agreement on the need for a flexible, modular HTA framework based on cross-stakeholder collaboration in HTA and assessing DHTs across the full lifecycle. HTA elements, such as clinical effectiveness and safety, organizational aspects, and DHT-specific attributes, such as usability, accessibility, and interoperability, should be assessed while considering innovative methods to generate evidence before market access and after the deployment of the technology.
- This research contributes to the broader policy environment unfolding within the context of the EU HTA Regulation, while providing stakeholder consensus principles to designing a harmonized HTA framework for the European Union.

Introduction

The integration of digital health technologies (DHTs) is accelerating across Europe, driven by increasing pressures on healthcare systems and growing expectations of accessible and efficient patient-centered care. These technologies can optimize resource use, enhance system responsiveness, and improve health outcomes.¹

Health technology assessment (HTA) has served as a decision-making support tool in assessing the value of new technologies. However, existing HTA methodologies in Europe have been primarily used to assess pharmaceuticals and high-risk medical devices, typically characterized by linear development and evidence generation pathways. In contrast, DHTs are characterized by diversity, rapid iteration cycles, and reliance on complex technical infrastructures. Many DHTs do not fit existing regulatory categories and are introduced often through alternative

pathways, such as procurement, pilots, or institutional innovation funding, bypassing traditional HTA processes.² Moreover, the criteria traditionally used to assess value (eg, EUnetHTA Core Model),³ such as clinical effectiveness, cost-effectiveness, and ethical, legal, and social implications, may require adaptation to reflect the unique attributes and novel attributes of DHTs, such as usability, interoperability, and long-term user engagement.^{4–6} Interoperability of digital health technologies is defined as their capacity to be securely accessed across health systems, enabling open, transparent exchange and meaningful use of information, including health-related data.

To make DHTs more accessible, several European countries are adopting a statutory reimbursement obligation by amending traditional assessment frameworks to fit the particularities of

DHTs.^{7,8} Germany's Digital Health Applications (DiGA) fast-track is a widely referenced example, offering manufacturers of low-risk DHTs the opportunity to gain temporary reimbursement while collecting real-world evidence.⁹ France's PECAN framework builds on this model by incorporating additional types of DHTs, including connected devices and remote monitoring tools, within an early access reimbursement track.¹⁰ In Belgium, the mHealthBelgium framework enables a multilevel assessment process, starting with technical validation and progressing toward functional and financial integration.¹¹ Other countries, such as Finland, Spain, and the United Kingdom are integrating DHTs with varying levels of formalization.¹²⁻¹⁴

Despite these developments, the broader picture remains fragmented. Significant differences can be observed in (1) the types of DHTs (risk-class, intended purpose, and end users) selected per country, (2) methods and assessment criteria, (3) stakeholder involvement considered during HTA, and (4) links to reimbursement models.¹⁵ Although in Germany fast-track supports access of low-risk health apps and web-based platforms, in other countries, such as France and Finland, they include telemedicine and artificial intelligence (AI) solutions. There are also considerable differences in the assessment criteria across European countries, and assessment outcomes vary, such as a multi-level tier system, traffic light system, or go/no-go decisions.¹⁶ Several HTA models have been described in the literature and some have been used as a guide for research studies on the value of DHT, eg, the Model for Assessment of Telemedicine¹⁷; however, they have not been implemented horizontally among national HTA agencies. These limitations are further compounded by the fragmentation of HTA practices across Europe, with national systems varying in institutional capacity, procedural maturity, and policy priorities.¹⁸ The lack of coordination not only affects market access of DHTs but also risks undermining the overall goal of providing timely access to DHTs via public funding across Europe.¹⁹

EDiHTA Project

Recognizing these systematic challenges, the European Digital Health Technology Assessment (EDiHTA) project was launched in 2024, funded by the European Commission (Horizon Europe) for 4 years.^{20,21} EDiHTA's mission is to map and address current regulatory and HTA barriers by developing a harmonized and flexible HTA framework tailored specifically to the unique characteristics of DHTs. This framework will enable the assessment of various DHTs, with different intended purposes also including AI solutions, while also considering different maturity levels and decision-making levels. EDiHTA brings together 19 partners from 10 European countries, including policy makers, HTA bodies, industry, patient organizations, and academic institutions. The goal of the project is to harmonize different standards relevant to the assessment of DHTs, while incorporating into the developed framework the perspectives of all relevant stakeholders. To this end, stakeholder involvement was embedded from the beginning, with participants contributing to the definition of key concepts, evidence requirements and practical considerations through consultations, and iterative feedback rounds.

Methods

The objective of this article is to identify points of agreement and conflict in the evaluation of DHTs as part of EDiHTA research that identified needs and requirements of key stakeholder groups relevant to the design of a harmonized European HTA framework. Stakeholder involvement focused on 5 groups identified as

central to the HTA process: national decision makers, HTA agencies/bodies, developers/manufacturers, healthcare providers, and patients. In line with the need for harmonization as identified by the European Commission, particular attention was paid to ensure diversity in country representation, covering different regions of Europe with varying levels of digital health and HTA preparedness. A stakeholders' network was identified through an internal EDiHTA workshop and was enriched by outreach at relevant conferences (Health Technology Assessment International, Healthcare Information and Management Systems Society, and European Health Management Association) and a snowball sampling approach to broaden participation. In total, 97 individuals with varied experience in using or evaluating DHTs participated in this exercise, representing a wide range of perspectives, including health ministries and payer authorities (for national decision makers), policy officers and practitioners from HTA agencies, both large-scale companies and early-stage developers (industry), hospital managers and clinicians (healthcare providers), and patient representatives.

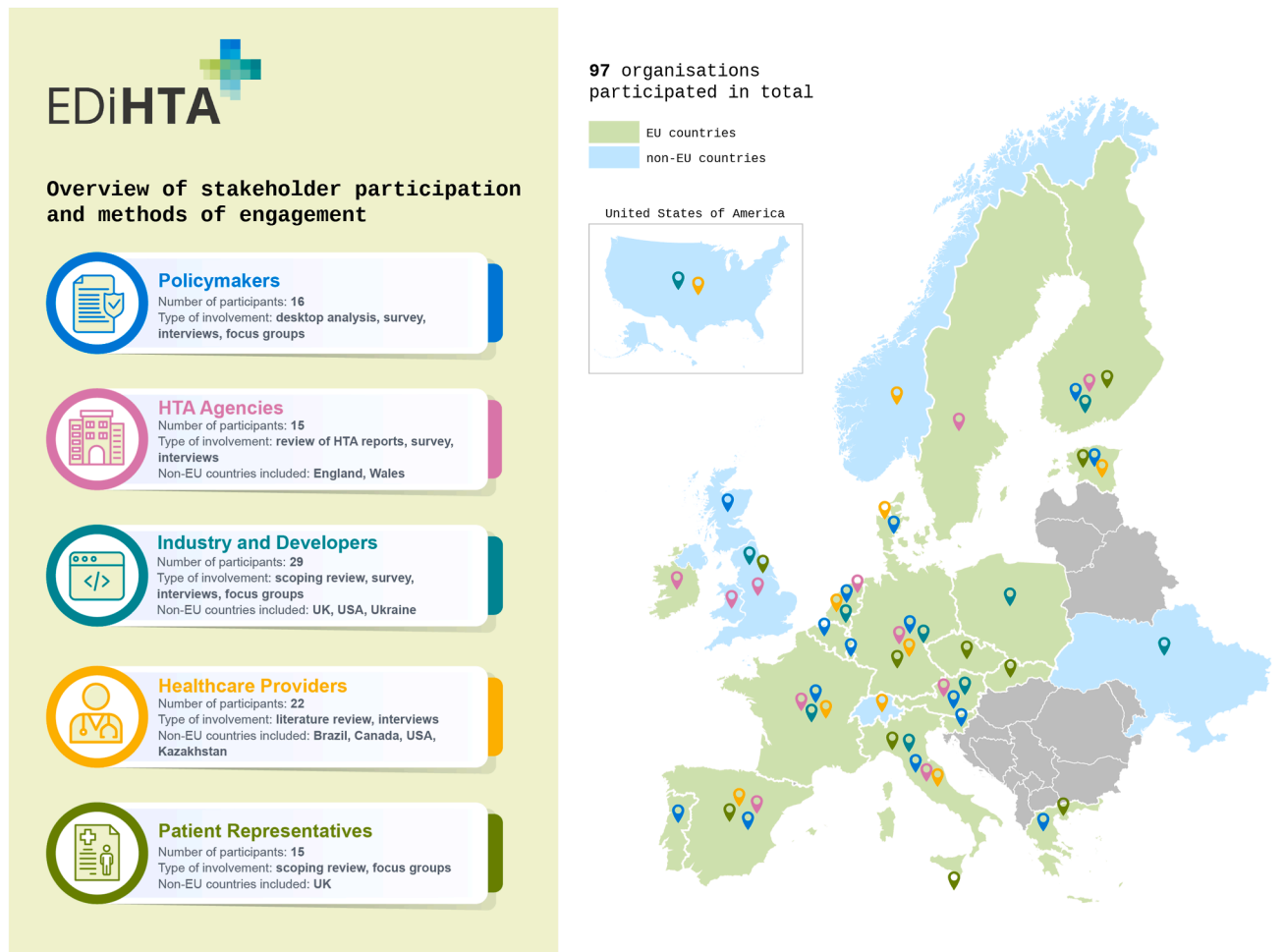
The Innovation Health Technology Assessment Methods framework was used to identify the role of relevant stakeholders and how they could be involved in a cocreation methodology to identify needs and requirements.²² The identification of roles in the innovation process (EDiHTA development) permitted an active and responsible stakeholder involvement while considering their perspectives and how to focus on what is needed to assess DHTs. To identify limitations in existing HTA methods, stakeholder input was obtained along with real-world practices to uncover implicit challenges. Using design thinking principles, EDiHTA process was envisioned to identify key conceptual principles, enablers and barriers. Comparing the future scenario with existing practices helped reveal gaps and diverse contextual needs across DHTs, disease areas, and regions.

A mixed-methods design was used to collect data from the stakeholder groups (Fig. 1).

- For 16 policy makers and regulators, an analysis of national e-health and digital health strategies was followed by surveys and interviews to understand how DHTs are currently evaluated and implemented, and how HTA might be structured to support national health systems' needs.
- After an analysis of national HTA reports for DHTs, 15 representatives of HTA agencies were interviewed using a standardized protocol, focusing on stakeholder involvement, evidence domains, and methodological priorities.
- For developers/manufacturers, a scoping review and survey informed 4 focus groups with 29 individuals: 1 with large-scale companies from MedTech Europe and 3 with small and medium-sized enterprises/startups. Five individuals were also interviewed because they failed to participate in the focus groups. The focus groups were segmented by technology type (AI, mobile apps, and telemedicine).
- Twenty-two healthcare providers were interviewed using multilingual protocols based on a pragmatic literature review, with a focus on institutional decision-making and local HTA practices.
- For patients and patient organizations, a scoping review and 2 focus groups with 15 participants were carried out in collaboration with the European Patient Forum. These sessions explored how patients define value and what criteria they consider central to person-centered assessment.

The protocols of literature review, surveys, interviews, and focus groups were developed with similar specifications to facilitate data extraction, thematic analysis, and evidence

Figure 1. Overview of stakeholder participation and methods of engagement.



synthesis for each and across all stakeholder groups. The evidence synthesis was carried out in step-wise process to identify the final conceptual framework of the themes that emerged and apply them to the development of the EDiHTA framework.²³ A thematic analysis was performed by 2 reviewers to analyze and synthesize the evidence retrieved, while specific considerations were made on consensus and conflict points regarding the evaluation of DHTs. Triangulation of data across the stakeholder groups was achieved with a logical sequence of the activities planned to map past and present while imagining the future. Desktop analysis and literature reviews allowed for past and present exercise across the groups and then surveys and interviews/focus groups were used to validate past and present techniques while imagining the future for each perspective. Although interviews/focus groups were structured in a similar way across groups, freedom of speech allowed participants to elaborate on novel contexts, aspects, and methods of assessment for DHTs while also considering strategies for harmonization.

Results

Through this research, we identified 5 main themes reflecting perspectives of stakeholders for the evaluation of DHTs. Agreement and conflict among stakeholders are considered in the sections below.

The Need for Harmonization

European nations show heterogeneity in digital maturity and national policy support of DHT implementation, creating barriers to the assessment of DHTs, which creates equity and efficiency issues for health systems. Yet, all stakeholder groups, including policy makers, HTA agencies, technology developers, healthcare providers, and patients, agree that there is a need for aligning HTA assessment methods across Europe.

Each stakeholder group brings its' own perspective on that point, with policy makers emphasizing that harmonization could streamline decision-making processes, enhance national health-planning, reduce duplication of assessment, and promote efficiency of DHTs implementation. This is particularly applicable in smaller countries or countries with limited resources and HTA capacity, such as Slovenia, Portugal, and Greece, as well as in wealthier countries, where managing system priorities can be equally complex (eg, Germany, France, and Belgium). Interviews with 15 HTA agencies across Europe revealed variation in methodological approaches used to assess DHTs. Therefore, agencies suggested that harmonization of an HTA framework may support the pooling of expertise and enhance cross-border collaboration, especially in cases in which individual agencies may lack the capacity to assess rapidly evolving or technically complex DHTs. At the same time, they also stressed the importance of retaining

flexibility and ensuring room for adaptation to national decision-making contexts and priorities. From the developers' perspective, the lack of consistency in regulations, HTA pathways, and reimbursement schemes across Europe was described as a major challenge, particularly for small and medium-sized enterprises with limited resources to navigate multiple national systems. Some expressed a preference for countries where clearer and more linear evaluation pathways exist and are also connected to reimbursement models, such as Germany (DiGA) or France (PECAN), potentially contributing to geographical imbalances in access to innovation. In this context, harmonization of an HTA framework for DHTs was perceived as a means of leveling the playing field. Patients expressed support for a common framework as well, suggesting that it may help reduce cross-country inequalities in access to DHTs.

Despite support for harmonization, stakeholders stressed that any European framework must remain flexible enough to accommodate local priorities while considering different maturity and decision-making levels.

Valued DHT Characteristics

In addition to broad support for harmonization, there was considerable interest in how and which technologies should be prioritized within the proposed framework. Stakeholders generally favored the evaluation of DHTs that are aligned with existing healthcare goals and that show potential for smoother integration into current health systems. Interoperability was frequently highlighted as a critical factor for effective adoption and use. Policy makers, healthcare providers, and developers emphasized that DHTs should be capable of functioning within existing digital health infrastructure. In cases in which technologies are not interoperable, stakeholders noted that adoption becomes significantly more difficult, and additional resources are often required for integration, training, or system redesign. Patient centricity was also commonly cited as a desirable feature. Healthcare providers advocated for DHTs that are easy to use, enhance engagement, and address individual needs and health contexts. They noted that even effective tools may fail if they are not compatible with clinical workflows, staffing structures, or IT infrastructure. Patients, similarly, expressed support for early involvement in the development phase and the inclusion of patient-centered criteria, including accessibility, ease of use, and personal relevance. Usability, such as intuitive interfaces, accessibility features, and adaptability to diverse user groups, was viewed as central to ensuring effectiveness and uptake. Although many stakeholders supported prioritizing DHTs that complement existing care pathways, there was also an openness to evaluating DHTs that offer innovative approaches. Tools that support underserved populations, introduce new models of care, or target emerging health challenges were seen as potentially valuable, even when they do not align directly with current service delivery frameworks.

Multistakeholder Collaboration

Stakeholders agreed that a comprehensive HTA framework for DHTs must be underpinned by structured and inclusive collaboration across all relevant stakeholders. Although the need for broad stakeholder involvement was uncontested, perspectives differed on how collaboration should be operationalized. Policy makers and HTA agencies suggested that existing frameworks provide valuable lessons but may require adaptation to better reflect the specificities of digital health.

Several HTA agencies noted limitations in technical expertise, particularly regarding AI tools, and welcomed efforts to address

this through institutional partnerships. To address these limitations, FinCCHTA, a Finnish HTA agency, has begun collaborating with Oulu University to outsource the technical evaluation of DHTs when necessary, ensuring access to domain-specific expertise while maintaining independence and objectivity in overall assessments. Developers echoed this, highlighting inconsistent evaluation standards and lack of familiarity with digital innovation among assessors, leading to unpredictable outcomes in HTA processes. Developers appreciated collaboration but raised concerns about protection of intellectual property, particularly relevant for startups fearing early-stage exposure. Some highlighted Belgium's mHealth framework as a successful collaborative model involving developers, patients and public health actors upon submission of a HTA dossier. Patients and healthcare providers emphasize the importance of user involvement to ensure that DHTs address real-world needs. Healthcare providers emphasized that locally implemented DHTs often bypass formal HTA, entering use through institutional procurement or clinical innovation channels. They called for HTA processes that integrate provider feedback and real-world usability assessments. Patients, asked for structured involvement as key to usability and uptake, suggesting codesign workshops and feedback loops embedded in HTA processes.

Principles of Concept Design

Across stakeholder groups, there was broad agreement that a harmonized HTA framework should be both flexible and scalable, supporting implementation of DHTs of different maturity levels across diverse health system contexts. Rather than enforcing a uniform model, stakeholders proposed a modular design, structured around core assessment components and expanded assessment with optional components, similarly to the EUnetHTA Core Model. Such a model would enable countries at varying levels of digital maturity to engage with the framework in ways that reflect their current capacities.

Several participants proposed that the framework allow for staged entry of DHTs, enabling earlier access under provisional conditions, with reevaluation as additional evidence becomes available. This approach, mirroring practices such as Germany's DiGA, was viewed to balance innovation with risk management. The concept of fast-track pathways also featured prominently in industry and HTA agency discussions. Stakeholders suggested that low-risk, low-cost, or already widely used DHTs, such as symptom checkers or scheduling tools might not necessarily require HTA or the same level of scrutiny as more complex or higher-risk DHTs, such as AI-supported diagnostics.

A consistent theme across stakeholder input was the importance of transparency and predictability. Developers highlighted the need for clear expectations, timelines, and entry points to guide planning and investment. HTA agencies emphasized the need for methodological consistency and safeguards to prevent the misuse or premature adoption of unproven safe or (cost)effective DHTs. Overall, modularity was seen not only as a technical feature but as a mechanism to build trust and support alignment while preserving national flexibility.

Stakeholders suggested that assessment criteria should be both structured and adaptable, considering the maturity, intended purpose and risk profile of DHTs. HTA agencies supported a proportionate approach, in which assessment criteria and requirements were tailored to life cycle stage or risk category, reserving more detailed assessment for more complex technologies. Several stakeholders called for the development of criteria sets tailored to different types of DHTs. For example, self-monitoring tools might be evaluated on usability and patient

outcomes, whereas AI-enabled decision support systems would require rigorous technical validation and performance benchmarking. There was also interest in ensuring that the criteria reflect the full lifecycle of a DHT. Stakeholders proposed that the framework support dynamic reassessment as technologies evolve, particularly important in the case of AI, for which algorithms may be updated after deployment.

There was broad support for the integration of real-world evidence (RWE) into the evaluation process. Developers viewed RWE as a more feasible and relevant alternative to controlled trials, particularly for tools already in use. HTA agencies and policy makers emphasized that RWE may help track performance in practice, supporting conditional or staged approvals. Patients and healthcare providers noted that RWE often reflect the complexity of daily use more accurately than randomized controlled trials. Across stakeholder groups, it was suggested that the EDiHTA framework offer guidance on how to incorporate RWE in HTAs in a way that is credible and transparent.

HTA Domains in Focus

While acknowledging the diversity of DHTs, stakeholders consistently supported the inclusion of a core set of domains in HTA evaluations, with room for adaptation where relevant.

Clinical effectiveness and safety emerged as a priority across all stakeholder groups. Policy makers, HTA agencies, and developers recognized these domains as essential to trust building and decision making, whereas providers and patients viewed them as critical to user confidence and outcome assurance. It was suggested that harmonized, transparent methods are needed to assess these criteria consistently across systems.

In addition to clinical safety, technological safety was also considered important. Data privacy and cybersecurity were universally acknowledged as essential, particularly by providers, patients and developers. Developers noted the importance of demonstrating European Union General Data Protection Regulation compliance and ethical data governance to secure user trust and market access. Patients, meanwhile, emphasized their willingness to share data (eg, for RWE generation) if safety, transparency, and control are guaranteed. Clarity on who accesses the data, for what purpose, and how consent is managed was highlighted as particularly important for patient empowerment.

Organizational impact was highlighted in discussions with providers, HTA agencies, and policy makers. The introduction of DHTs often involves changes in staffing, workflows, and resource allocation. Challenges during the evaluation phase may result in underutilization or resistance at the point of care. The EDiHTA framework should therefore identify key organizational factors to strengthen the assessment of this aspects, while also considering differences, priorities and scalability across different levels of the health system from large tertiary hospitals to smaller community care settings.

The characteristics of DHTs should be brought more into the light during the assessment with aspects such as interoperability, usability, and interpretability that were described as a precondition for meaningful adoption. Stakeholders noted that digital tools that cannot integrate into existing infrastructures are unlikely to scale, regardless of their clinical merit. Stakeholders emphasized that these aspects should not be treated as stand-alone features but rather addressed across multiple HTA domains, including technical performance, organizational and feasibility along with the social related contextual characteristics. The user experience, also emerged by patients, providers and policy makers as a transversal characteristic that should be considered during the assessment and for the full lifecycle of the DHT.

Policy makers and HTA agencies also suggested that social aspects could bridge the gap between organization aspects and user experience, while assessing the impact of the DHT in health equalities with aspects such as digital literacy. Most interviewees noted the emerging use of AI in healthcare and stressed that ethical aspects should address whatever the currently emerging regulations around AI cannot.

Finally, some stakeholders suggested that, particularly for DHTs introduced through fast-track or conditional pathways, the reassessment of clinical, economic, and organizational value is necessary when more evidence becomes available. In this context, building robustness around these aspects could use post-market evidence in the form of real-world data.

Discussion

Toward a HTA Framework for DHTs

The findings of this study suggest that despite the heterogeneity of healthcare systems across Europe, there is a shared recognition among stakeholders for the need of a more coordinated approach to the evaluation of DHTs. Alignment was observed on several elements, but differences remain in how various groups interpret value and prioritize HTA processes. Although policy makers and HTA agencies often prioritize clinical effectiveness and alignment with national priorities, developers however advocate for proportionate, iterative evidence standards that accommodate the modular and fast-paced nature of digital innovation. Patients and providers place emphasis on usability and real-world outcomes, echoing findings from other recent work stressing the importance of user relevance in HTA for digital tools.^{2,24}

These discussions also underscored the limitations of traditional HTA models when applied to dynamic, modular technologies.²⁵ Stakeholders found traditional HTA methods unable to assess the full value of DHTs that evolve rapidly. In response, there was strong support for modular, staged evaluation framework, which could allow provisional access and reassessment as evidence matures. RWE was considered central to this approach, particularly for iterative tools in the postdeployment phase in which iterative evidence generation is required. However, concerns remain about RWE governance, transparency, and methodological consistency, challenges echoed in literature.²⁶ Participants also highlighted the need for frameworks to offer clearer timelines, predictable decision points and a structured focus on key aspects most relevant to DHTs, such as usability, interoperability, and organizational impact. These preferences align with recent reflections, which call for increased modularity, faster assessment processes, and expanded evaluation criteria for digital tools.^{27,28} Collectively, these insights point to the importance of structured involvement across stakeholder groups to surface areas of friction early and codevelop methodological solutions.

Building on this research, the EDiHTA project will integrate the findings into the conceptual principles of its newly developed framework. To ensure alignment and harmonization, a stakeholder workshop will be convened with 50 participants from diverse groups and countries to evaluate the framework and its indicators, focusing on the comprehensiveness and appropriateness of assessment criteria. Feedback will guide refinement before piloting the framework in external use cases, involving all relevant stakeholders in assessing 3 DHTs while new indicators will be introduced to capture stakeholder collaboration in decision making throughout the assessment process. These efforts unfold within the broader policy context of the EU HTA Regulation (EU 2021/2282), which aims to harmonize clinical assessments across Member States. Although its current scope excludes most DHTs,

countries are exploring pathways for voluntary coordination in context of the regulation in this field.²⁹ In this context, the EDiHTA project may not only support the codesign of a harmonized HTA framework for DHTs but also contribute to the broader policy environment demonstrating how stakeholder consensus can be operationalized through modular, flexible approaches.

Because of the nature of this research to address needs and requirements at a concept level, the stakeholder sample was relatively small and composed primarily of stakeholders already engaged in HTA activities. This could bias the results; however, main principles were needed to be established to further develop the EDiHTA framework, and this was achieved with a cross-country approach for all stakeholder groups. Furthermore, the coordinated approach of data collection, triangulation, and evidence synthesis across all stakeholder groups facilitated the extraction of key concepts and themes, highlighting areas of agreement and conflicts that will strategically be considered in the development of the EDiHTA framework.

Conclusions

Our findings suggest that although the evaluation of DHTs present unique challenges, there is strong cross-stakeholder agreement on the need for a more coordinated approach. The heterogeneity of current HTA systems was identified as a strong barrier to promote equitable, efficient, and high-quality health systems. The EDiHTA project embraces a flexible, cocreated approach to developing a framework for Digital HTA, prioritizing stakeholder involvement and real-world applicability over rigid harmonization. The process follows an incremental, multistep strategy that began with identifying broad needs and requirements, followed by targeted literature reviews and consultations with domain experts to develop evidence requirements and address existing gaps. The framework will undergo multiple rounds of piloting, initially at 6 internal hospital-based sites, and subsequently with 3 external DHTs through an open call. These pilots aim to evaluate feasibility, usability, and the framework's capacity to integrate diverse stakeholder perspectives in real-world settings. This iterative approach fosters continuous refinement through observation and feedback, ensuring contextual relevance and value recognition. EDiHTA embeds flexibility through modular design, enabling local adaptation and progressive implementation while respecting national healthcare priorities and capacities. Ultimately, this work contributes to the broader effort to build consensus on how DHTs could be assessed in a standardized way that is both rigorous and inclusive.

Author Disclosures

Author disclosure forms can be accessed below in the [Supplemental Material](#) section. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union the European Health or the Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

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Author Affiliations: Università Cattolica del Sacro Cuore, Graduate School of Health Economics and Management (Tsiasiotis, Mezei, Di Bidino, Basile, Cicchetti, Sacchini); Óbuda University, Innovation Management Doctoral School (Mezei); Policlinico Universitario Agostino Gemelli, Operating Unit of Health Technologies (Di Bidino); Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS), Operating Unit of HTA (Battaglia, Cicchetti); European Patients' Forum (Strammiello); Odense University Hospital, Centre for Innovative Medical Technology (Kidholm); Radboud University Medical Center, IQ Health Science Department (Oortwijn); Università Cattolica del Sacro Cuore, Research Centre for Applied Bioethics and Medical Humanities (CRIBCeMH) (Sacchini).

Correspondence: Emmanouil Tsiasiotis, MPH, The Graduate School of Health Economics and Management (ALTEMS), Università Cattolica del Sacro Cuore, Rome, Italy Roma. Email: emmanouil.tsiasiotis@unicatt.it

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